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Improving the standards of living donor kidney transplantation

Jennifer A Lumsdaine

**PhD By Research
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List of abbreviations

BSA	Body Surface Area
CCI	Creatinine Clearance
CCICG	Creatinine Clearance estimated by Cockcroft-Gault
CMV	Cytomegalovirus
CT	Computed tomography
DVT	Deep Venous Thrombosis
EBV	Epstein Barr Virus
FACS	Flow cytometry
GFR	Glomerular Filtration Rate
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
IMA	Independent Medical Assessor
NHS	National Health Service
MRA	Magnetic Resonance Angiogram
PMP	Per Million Population
QALY	Quality-adjusted Life Years
SCr	Serum creatinine
UK	United Kingdom
UKT	United Kingdom Transplant
USA	United States of America
ULTRA	Unrelated Live Transplant Regulatory Authority
WHO	World Health Organisation
WHOQOL	World Health Organisation Quality of Life
WHOQOL-BREF	World Health Organisation Quality of Life Short form

Declaration:

I hereby declare that this thesis has been composed solely by myself and that the work described herein was my own except for the contribution of others indicated and acknowledged.

Jennifer Lumsdaine
27 March 2006

Abstract

To receive a kidney from a living donor is recognised as one of the optimum forms of treatment for end-stage renal failure. In addition, the shortage of organs from cadaveric donors has resulted in living donor numbers increasing to compensate for the shortfall. Nevertheless, for an individual to undergo a major operation for which there is no clinical indication requires the risk/benefit ratio to be acceptable. This thesis explores aspects of living donor kidney transplantation to establish current practice and identify areas for improvement. The aims of the study are:

- To establish the living donor assessment, selection criteria and follow up practice throughout transplant units in the United Kingdom
- To measure the impact on quality of life and relationship issues for both donor and recipient
- To ascertain if the act of donating a kidney causes short or long term physical or psychological harm
- To determine the optimum follow-up practice for living donors
- To explore whether the standards of living donor transplantation can be improved

The study methods included a prospective, longitudinal study utilizing quality of life tools and specific relationship questionnaires, detailed surveys of transplant units in the UK concerning assessment and follow-up and a retrospective study of post operative complications. Additional work investigated insurance companies attitudes to living donors.

Results showed that there remains variety in practice throughout the UK in procedures, although publication of national guidelines has provided a valuable framework. This study has demonstrated that with rigorous donor assessment only those above UK average physical quality of life scores proceed to donation. The donors experience a transitory decrease in quality of life following the operation and have a small risk of major and a higher risk of minor complications. Longer term the donors are not compromised by physical or psychological difficulties and experience an improved relationship with the recipient. Annual follow-up is provided for those donors who wish to attend and the majority of donors do not worry about living with one kidney.

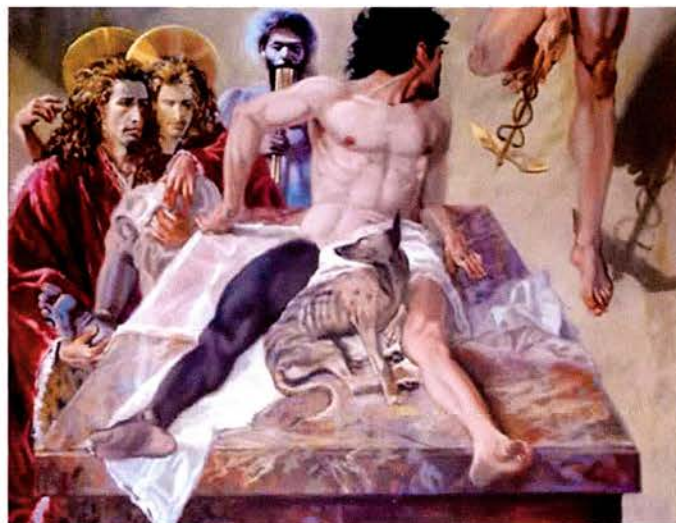
The clinical benefits of living donor transplant for the recipient are well-recognised. The assessment process appears to preclude those who may suffer psychological impairment from receiving a kidney from a living donor in this study group. The recipient enjoys an improved quality of life and relationships with both the donor and other family members. Initial high level of concern about the donor decreases after the operation.

Careful donor and recipient selection results in successful outcome and should encourage living donor transplantation to increase throughout the UK.

CHAPTER 1: INTRODUCTION

1.1: The History of Transplantation

Transplantation has been described as the most stirring event of the past century in the field of medical science. Yet the concept of removing an organ or tissue from one person and transplanting it into another can be traced as far back as the 13th century. Two physicians, Cosmas and Damian replaced the cancerous leg of a church sexton with the leg of a recently deceased man, and were subsequently honoured as patron saints of physicians and surgeons¹.



*Contemporary representation of SS Cosmas and Damian painted by Durand
Copyright www.Durand.com*

As is clear from the painting above, the basic concepts of vascular perfusion and rejection which underpin modern day transplantation were not understood and it is

almost certain that the black limb sutured to the sexton's leg deteriorated very rapidly. Indeed it is very unlikely that the recipient of this limb was able to sit up as portrayed in this painting. Although many myths and legends were founded on the idea of transplantation, it was not until the 20th century that the concept became a reality.

In 1906 in France, Alexis Carrel from Lyons was leading the field in vascular surgery. He developed the technique of anastomosing blood vessels together to allow blood to circulate – this heralded the possibility of using this technique with organs². He established a series of principles for successful vascular anastomosis that hold good today. Subsequent work with dogs resulted in a successful autograft - transplanting the dog's own kidney from its normal site in the retroperitoneum to the dog's neck³. Perhaps most famously he innovated the practice of removing a patch of the donor aorta suitable for grafting onto another site – this was subsequently named the 'Carrel patch'⁴.



*Alexis Carrel- The pioneer of techniques for vascular reconstruction and anastomosis who was awarded the Nobel Prize in Physiology or Medicine in 1912. Photograph copyright of the Nobel Prize organization
<http://nobelprize.org>*

In 1933 in Russia, Yu Yu Voronoy performed the first renal transplantation in man¹. Although it was not successful he continued to treat six further patients with kidneys from cadaveric donors, none of which worked due to lack of recognition of the effect of warm ischaemia on the kidney⁵. In Paris in the early 1950s surgeons attempted a living donor transplant on a young man who had lost his kidney due to an accident and transplanted his mother's kidney. There was initial function, however the kidney stopped working after a few days¹. Lessons were being learnt from these experimental procedures – future transplants would use the surgical technique practiced in Paris of transplanting into the iliac fossa³

In parallel with the clinical work, investigators were studying the effect of the immune system on the fate of transplanted tissues². There was a pressing need to develop techniques for repair of superficial injuries sustained from burns during battle and this provided the impetus for early research into the immunology of transplantation. Medawar in association with Billingham and Brent undertook a carefully structured series of experiments based on skin grafting and were able to demonstrate immunological rejection, accelerated rejection and acquired immunological tolerance. Sir Peter Medawar's work describing rejection, immunological memory and tolerance earned him the Nobel Prize in 1960².



Sir Peter Medawar- Arguably the Father of Transplantation Immunology awarded the Nobel Prize for Physiology or Medicine in 1960.

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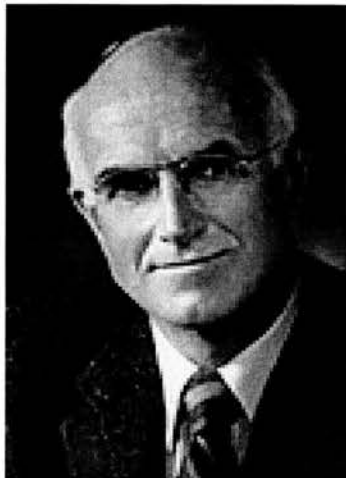
At a similar time to Medawar's discoveries of immunological rejection, George D Snell identified histocompatibility antigens in the mouse and this provided the basis for antigenic identity of strains and individuals⁶. The Human Leucocyte Antigen (HLA) system was discovered by Jean Dausset, for which he received the Nobel prize in 1980⁷, although the clinical significance of these findings for transplantation was not apparent at the time².



George D Snell

Identified the phenomenon of species and strain identity with the discovery of histocompatibility antigens in the mouse

It was Joseph Murray in Boston who successfully transplanted a kidney from one identical twin to another at the Peter Bent Brigham Hospital in 1954⁸. Skin grafting was attempted prior to transplant to confirm that the twins were monozygotic, even the local police station helped out by checking fingerprints (the media were reassured that though the fingerprints were very similar there were differences identified)⁹. Murray and his colleague Merrill used the intra-abdominal technique as devised by Kuss in Paris in 1951¹. The success of this transplant demonstrated that renal transplantation was a technically feasible procedure¹⁰.



Joseph Murray

Transplanted the first kidney successfully between identical twins at Brigham and Womens Hospital Boston 1954. He was awarded the Nobel Prize for Physiology or Medicine in 1990.

Photograph copyright of the Nobel Prize organization <http://nobelprize.org>

Up until this time the development of renal failure had been associated with a slow and inexorable decline leading to death. Renal dialysis was in its infancy and because of the rudimentary nature of the procedure, the high risk of infection or chemical poisoning, dialysis itself was an extremely hazardous and ineffective treatment compared with modern day dialysis¹¹. The importance and the benefit arising from successful renal transplantation should not therefore be underestimated. In the United Kingdom the most

active proponents of transplantation at the time were based in Edinburgh. Professor Michael Woodruff was leading the development of renal transplantation in Edinburgh and his team performed the first successful kidney transplant (between identical twins) in the UK in Edinburgh in 1960. The donor and the recipient (with a functioning graft) lived for 6 years and both subsequently died from stomach cancer within months of each other¹²¹³.



*Professor Sir Michael Woodruff
who performed the first successful
renal transplant in the United
Kingdom in 1960 between the
“Leith twins”.*

Thus, for patients with end stage renal failure with an identical twin willing to donate, transplantation became a reality. Clearly this represented a small minority of patients. Work began in earnest to overcome rejection, and total body irradiation was the first step towards suppressing the immune system to stop rejecting foreign tissue¹. Early immunosuppression relied on whole body gamma-irradiation and large doses of steroids to prevent rejection⁶. Such was the toxicity of these regimens that patients were required to be incarcerated for weeks at a time in sterile units being barrier nursed with little or no contact with the outside world. Furthermore, the risk of infection was very real and often

fatal in patients rendered effectively lymphopenic ^{2;8}. Maintaining the delicate balance between rejection and infection continues to challenge transplantation to this day.

In the 1960s Calne and Zukoski showed that 6-mercaptopurine (an anti-cancer drug) and one of its derivatives (azathioprine) could prevent rejection in renal allografted dogs⁵. These drugs were introduced to clinical practice in combination with corticosteroids in the 1960s by Calne, Hutchings and Elion as the primary immunosuppressants for all transplant patients and was used until the late 1970s². In 1978 Calne introduced the clinical use of the drug cyclosporine in Cambridge, UK⁵. Since that time newer immunosuppressants such as tacrolimus, mycophenolate mofetil, monoclonal antibodies and rapamycin have all impacted on outcome ^{2;14;15}.

Preservation of organs for transplants was another hurdle to overcome. The first discovery of fluid to preserve organs was almost an incidental finding by Dr Belzer in the USA in 1966. He had stored plasma overnight and filtered out the lipid layer that had formed, leaving clear plasma that could be used for kidney perfusion¹⁶. The Collins solution was subsequently developed by Dr Jeffrey Collins allowing kidneys to be preserved for over 12 hours¹⁷



Professor Sir Roy Calne, who pioneered many of the major advances in immunosuppressive therapy including 6-mercaptopurine, azathioprine and cyclosporine A. Calne also performed the first successful deceased donor renal transplant in the United Kingdom in 1962.

In order to become an established clinical therapy transplantation had to overcome many barriers; refining the surgical technique and overcoming acute rejection and avoidance of lethal infectious complications of immunosuppression². The early transplants succeeded due to a convergence of several factors – the kidney as a paired organ, an identical twin with chronic renal failure and an unaffected twin willing to donate¹⁸.

1.2: End Stage Renal Disease

As early as the mid 1800s, the foundation for modern renal medicine was being laid. In 1861 Professor Thomas Graham from Glasgow extracted urea from urine by filtering through a vegetable parchment coated with albumin. He called this process ‘dialysis’¹⁹. An artificial kidney was developed by Abel in Baltimore in 1913 but never used to treat a patient^{19;19}. It was not until 1943 that W J Kolff treated a patient therapeutically with

the invention of the rotating drum dialyser in the Netherlands, a model that was to be modified and used worldwide over the next few decades for selected patients²⁰. Unfortunately, the demand for treatment outweighed the number of dialysers available and still many patients died from acute or chronic renal failure. Thus, before the 1970s, therapeutic options for patients with end stage kidney failure were limited. Few dialysis facilities had been established and kidney transplantation was in the early stages of development as a viable option.²¹.

In 1972 the Social Security amendments in the USA provided financial support for the care of patients with end stage renal disease. By the mid 1980s, as dialysis facilities had increased to accommodate the growing number of patients with renal failure, Medicare mandated evaluation of all renal patients as transplant candidates¹⁸.

Here in the UK the number of people requiring renal replacement therapy also continues to grow - the annual acceptance rate for renal replacement therapy increased from 20 per million population (pmp) in 1982 to 101 pmp in 2002²², and by the end of 2002 over 37,000 patients in the UK were being treated for end-stage kidney disease²³. In 1981 the number of patients on renal replacement therapy (including transplant) in Scotland was 469, this number increased to 3286 by 2001²⁴. Currently the estimated global dialysis population is over 1.1 million and will be 2 million by 2010²⁵.

This rise in referral of patients with renal disease may in part be explained by the ageing population and wider criteria for acceptance onto renal replacement therapy than

previously²². In addition, the incidence of diabetes mellitus is rising dramatically worldwide – in 2001 it was estimated that 150 million people had diabetes mellitus with this increasing to 220 million by 2010²⁶. Approximately 40% of people with type II diabetes have microalbuminuria – an independent risk factor for progression of chronic kidney disease²⁵.

Table 1 shows the adjusted incident rates per million population of causes of renal failure in Scotland in 2002²⁷.

Table 1: Adjusted incident rates per million population of causes of renal failure at Day 1 in Scotland in 2002 - Scottish Renal Registry data

Cause of renal failure	PMP	%
Glomerular nephritis	15.8	15
Pyelonephritis	10.1	9
Polycystic kidney disease	6.7	6
Diabetes mellitus Type I	11.9	11
Diabetes mellitus Type II	7.1	7
Hypertension	3.2	3
Renal Vascular Disease	9.7	9
Misc/Unknown	43.5	40

Incident rates per million population of causes of renal failure in Scotland at Day 1 and percentage of causes of renal failure- total number 548 (108.4 pmp)²⁷

1.3: The cost of renal failure today

1.31: Medical costs

Since the introduction of therapeutic dialysis in the 1940s there have been many technical and medical advances. However even the most efficient dialysis regimens today provide only 10-12% of the small-solute removal of two normally functioning kidneys²¹. It has been estimated that cardiovascular disease mortality is increased approximately ten fold among patients with end stage renal disease²⁸. Associated complications of renal failure include anaemia, uraemia, hypertension, fluid retention and left ventricular hypertrophy. Patients suffer symptoms such as tiredness, headaches, anorexia and weight loss²⁹. Treatment of these symptoms has improved significantly. Anaemia is better managed with recombinant erythropoietin therapy, new synthetic dialysis membranes increase the overall efficiency of haemodialysis and peritoneal dialysis equipment is constantly being refined to reduce bacterial infection risk³⁰.

However, mortality rates and incidence of co-morbid diseases remain high for patients with end stage renal failure. Data from the European Renal Registry (34 countries) shows that the 6 year survival of non-diabetic patients on dialysis (>60 years old) is 40 per cent, this is reduced to 20 per cent in diabetics. Cardiovascular mortality increases by 10 folds in patients with end-stage renal failure³¹, with vascular diseases accounting for 15 per cent of deaths in patients. Malignant disease is about three times more common in patients on dialysis than in age- and sex-matched controls³². Long-term complications of dialysis also include hyperparathyroidism, bone disease, hypertension,

loss of sexual function and general fatigue and malaise²¹. Although dialysis is reasonably efficient at removing small solutes *e.g.* potassium and urea, middle-sized molecules such as proteins are poorly cleared and the endocrine functions of the kidney are not replaced by dialysis³³. Consequently, it is often only with a functioning transplant that the patient will regain the ability to produce erythropoietin, adequately clear small and middle molecules and improve blood pressure control.

An analysis of 73,103 adult transplant recipients in the United States concluded that longer waiting time on dialysis is a significant risk factor for graft survival and patient death. Mortality risk (defined as probability of survival at 5 years) after transplant when waiting >48 months is 72% compared to 21% if the transplant is performed pre-emptively³⁴. Further studies compared the outcome of paired donor kidneys, allocated to patients who had end stage renal disease for more than two years compared to patients who had end stage renal failure for less than 6 months. The graft survival in patients who had experienced more than two years of dialysis was significantly worse at 10 years (29% compared to 63% for patients who dialysed for less than 6 months)³⁵.

1.32: Social costs

Alongside the medical complications of end stage renal failure are the aspects pertaining to day to day living. These are not separate – fatigue and malaise are the most common complaints of patients on dialysis, along with the time spent on renal replacement therapy and diet and fluid restrictions. Body image is also affected due to the presence

of dialysis access device, oedema and changes in skin appearance in some patients³⁶. Many patients also have fertility difficulties, with women either having conception problems or premature birth, and impotence a common issue for males with renal disease. Patients do manage to continue to work as they did prior to developing renal failure, unless the job is very heavy. Some find the commitment of dialysis and associated symptoms affects their ability to work and socialize as before, and travel and holidays become far more difficult to organise. There are now a considerable number of studies using different measurement tools confirming that quality of life is adversely affected by end stage renal failure³⁶⁻³⁸, some also examine the effect of modality of treatment, and the time on dialysis³⁹. A study of over 17,000 dialysis patients worldwide concluded that there was a higher risk of death and hospitalization in patients with low quality of life scores, independent of demographic and co-morbid factors⁴⁰.

Being on dialysis does not only affect the patient but also family and friends. The commitment to treatment, restriction in activity and the on-going symptoms place a responsibility on the close family, most notably parents of young patients and partners within family units.

1.33: Financial costs

Three percent of the NHS budget in the UK is spent on kidney failure services⁴¹. in the mid 1990s the estimated total cost per year for home haemodialysis was £19,300 compared with £21,000 and £22,000 for haemodialysis in a satellite unit and hospital

respectively⁴². The cost of a kidney transplant was £17,000 per patient per transplant with a maintenance cost of £5,000 for immunosuppression per patient per year^{41;42}. Thus the cost-benefit of a kidney transplant compared to dialysis over a period of 9 years is £128,000 or £14,200 per year for each year the kidney is functioning⁴¹. This data should be used as leverage for investing in organ donation and transplantation programmes where, unusually for the NHS, the shortage is not of money but organs.

1.4: Kidney Transplantation

Regrettably deceased donor rates in most countries worldwide cannot meet the demand for transplantation. Although increasing living donor transplant rates have improved this situation there remains a shortage of renal allografts in virtually every country in the world.

There has been a slow but steady decline in the number of heart beating ventilated deceased donors over the last ten years in the UK, due to fewer deaths from road traffic accidents, better management of intra-cranial haemorrhage and a relative lack of intensive care unit beds, thus precluding patients deemed by radiological investigation to have a very poor/fatal prognosis from having assessment for brain stem death⁴³. Attempts to reverse the trend in deceased donors have been made by looking to non-heartbeating donors as a further source for kidneys suitable for transplantation. The number of non-heartbeating donor kidney transplants in the UK has risen from 38 in 2000 to 87 in 2004⁴⁴.

Countries such as the United States of America have continually increased the percentage of living donor transplants and this would suggest that there is scope for improvement in the living donor rates in the United Kingdom (Figure 2; Table 2). Any

attempt to improve numbers should not be at the detriment of either donor or recipient, and as enthusiasm increases donor safety must always take precedence.

UK Transplant have invested in both non-heartbeating and living donor programmes throughout the UK and the previous decline in organ donation and transplantation has recently been reversed, as displayed in Figure 1 ⁴⁵.

Figure 1: Number of deceased donors and transplants in the UK, 1995-2004 and patients on the transplant lists⁴⁶

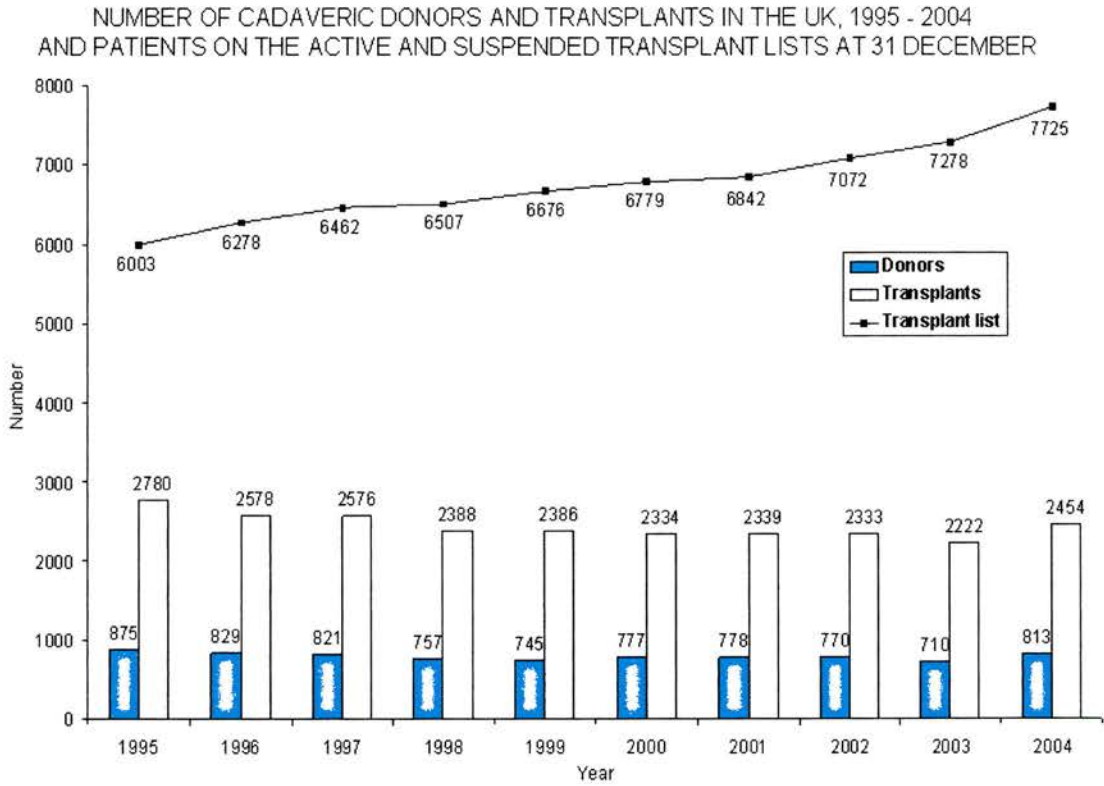
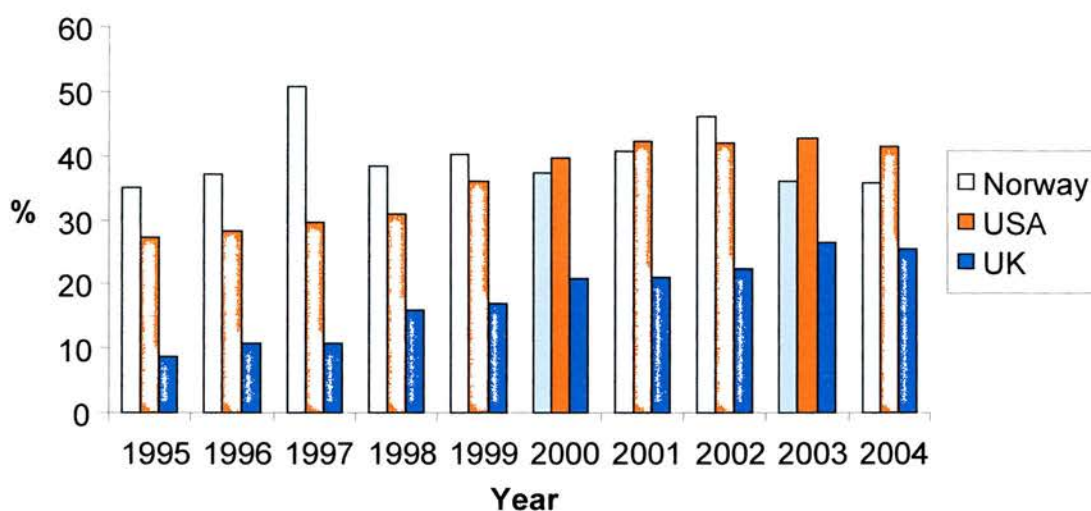


Figure 2: % Living donor of total number kidney transplants – Norway, USA and UK 1995-2004



Comparison of percentage of living donor transplant rates in Norway, USA and UK 1995-2004

Table 2: Total number of kidney transplants for 10 year period 1994-2004 - Norway; USA and UK

Country	Cadaveric	Living	Total	% Living donor
Norway	1246	806	2052	39.3%
USA	85510	49321	134831	36.6%
UK	13788	3031	16819	18.0%

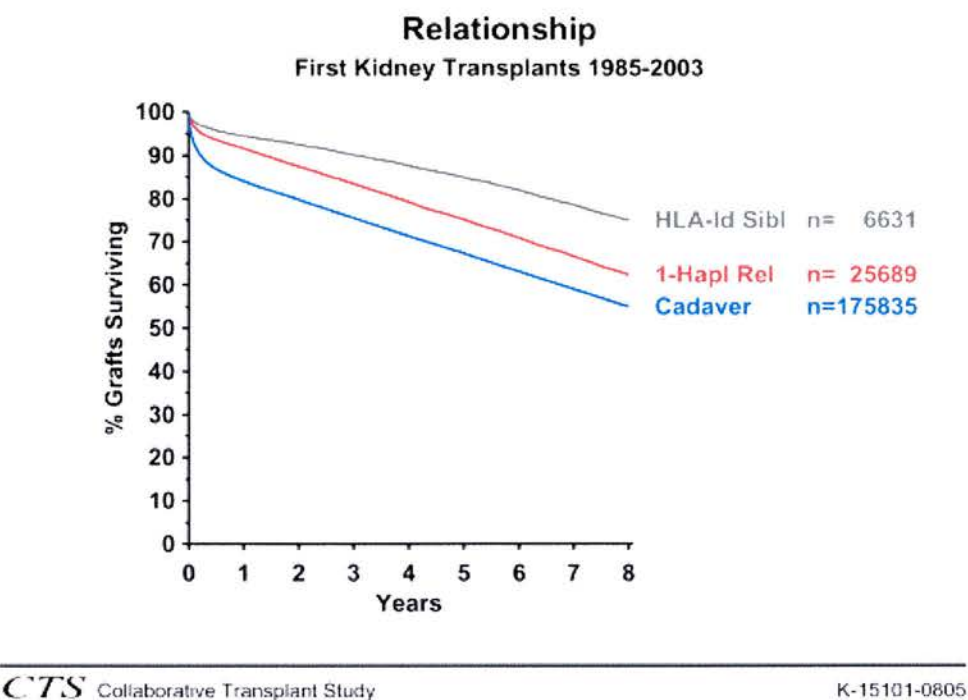
1.5: The Living Donor

Large studies have shown that the long term graft survival of a kidney from a living donor exceeds that of a deceased donor. An analysis of 93, 934 renal transplants in the USA from 1988-1996 showed in 1995 the projected half-life for grafts from living donors was 21.6 years compared to 13.8 years for grafts from deceased donors⁴⁷. Table 3 displays European results from the Collaborative Transplant Study⁴⁸. These better long-term results from living donors are explained by the quality of the organs. Potential living donors are extensively investigated with particular regard to renal function, and significant co-morbidity is excluded. The kidneys come directly from a physiological environment without the metabolic consequences of intra-cranial trauma and cerebral death. There is minimal cold ischaemia (a median time of 1 hour) compared with a median of 20 hours for deceased donor grafts⁴⁹. From the point of view of the recipient, there is the convenience of selecting a time that fits in with domestic and work commitments. Furthermore, there is the ability to proceed to pre-emptive transplantation and avoid the need for dialysis altogether, which has been proven to be the optimal therapy for patients with end stage renal disease³⁴. Deceased donor transplantation can be also be pre-emptive but some clinicians feel uncomfortable with the knowledge that this action may not be seen as fair to patients who have been on a transplant list for many months⁵⁰.

There is clear clinical evidence that, for the recipient, a living donor transplant is the best option. The difficulty arises with the complex ethical issues surrounding the removal of

a healthy organ from a fit person and exposure of that individual to the risk of serious complications. It is important to listen to the recipient who feels uncomfortable with the possibility of a relative undergoing such an operation on their behalf. Despite this, we still may adopt, especially with younger people when a parent is considering donation, a paternalistic attitude of knowledge about the best option based upon clinical data.

Figure 3: Graft survival of first kidney transplant



Graft survival of kidney transplant depending on relationship, comparing kidneys from HLA identical sibling, one haplotype matched relative and deceased donors⁴⁸

Respect for an individual's autonomy is the basic ethical concept that gives each person the right to consent to, or refuse, treatment⁵¹. However, individuals should be given the necessary information about the choices available and the potential consequences of each course of action. Whilst the potential donor may be given an appropriate, detailed description of the risks of donation, it is much less clear that all donors will listen. There may be a tendency for some people to decide at an early stage that they wish to donate and then to be impervious to any suggestion that they should make a more informed decision in the light of further counselling⁵². The consent may be real but whether it is truly informed, is questionable⁵³. It is also important to recognise that the clinical team involved also have rights as well as responsibilities. If a fully informed donor wishes to proceed with a course of action that involves risks of mortality or morbidity greater than the team find acceptable, they are under no obligation to proceed.

Although the quantified risks of donating a kidney are low for this group of carefully selected individuals, serious complications have a disastrous impact on the immediate donor and recipient family, but also on national programmes. The death of a live liver donor, Mike Hurewitz, in Mount Sinai Hospital in New York in 1999 caused negative media publicity and the temporary cessation of living donor liver transplants at that hospital⁵⁴.

Living donor transplantation requires a balance. The BTS Guidelines state there should be minimum risk to the donor with maximum benefit to the recipient⁵⁵. How do we ensure this in both the short and long term? How do we balance the complex issues of

autonomy and non-maleficence? This study aims to explore both the physical and psychological effects of living donor kidney transplantation on both donor and recipient.

1.6: Aim of study

- To establish the living donor assessment, selection criteria and follow up practice throughout transplant units in the United Kingdom
- To measure the impact on quality of life and relationship issues for both donor and recipient
- To ascertain if the act of donating a kidney causes short or long term physical or psychological harm
- To determine the optimum follow-up practice for living donors
- To explore whether standards of living donor transplantation can be improved

CHAPTER 2: ASSESSMENT OF THE LIVING KIDNEY DONOR

2.1: Introduction

The act of removing a well-functioning organ from a healthy individual for the benefit of another is a challenging concept and one that the transplant surgeon has to feel justified in doing on both medical and moral grounds. Inherently this is in direct conflict with the Hippocratic Oath of '*primum non nocere*' – first do no harm⁵⁶. However, living donor transplantation reaches beyond purely clinical factors. The surgeon has to assess the risk/benefit balance for the individual, examining the medical, social and psychological issues involved in each unique case⁵⁷. Although the final responsibility lies with the surgeon removing the organ, a team of health professionals assists with the evaluation process to reach the decision whether to proceed⁵³. Ultimately, only when consent by the potential donor and recipient is combined with the agreement of the team of health professionals that the balance of 'minimum risk to the donor and maximum benefit to the recipient' has been met, will living donor transplantation proceed⁵⁵.

2.1.1: Assessment criteria

The potential living kidney donor is requesting to undergo an operation that they do not need on clinical grounds, will temporarily disable them, and will leave them with a solitary kidney for life. The selection of individuals suitable to donate is therefore of paramount

importance. It is somewhat surprising, therefore, that there is no worldwide consensus on how these individuals should be selected. International studies, both in Europe and the USA have shown substantial variability in methods of evaluating potential donors⁵⁸⁻⁶³. It is recognised in transplant units throughout the world that variation in centre practice that some donors may be inappropriately accepted or denied⁶⁴. The reasons for inappropriate selection may be manifold but include some pressures which are outwith purely clinical motivation. These include commercial pressure in the case of the privately insured, pressure and inappropriate involvement from the doctor responsible for the potential recipient and operations in some third World countries done for commercial benefit to donor. Bia *et al* discussed the importance of examining current practice patterns and defining issues that need further study in their report on the practice of living donor assessment in the USA⁵⁸. Veitch reported that the evaluation of live donors in the UK was not based on any experimentation or clinical trial⁵⁹. As living donor transplantation continues to increase across the world, data is required to prove that donor nephrectomy is a safe option for an individual in both the short and long term.

Although lack of consensus persists concerning who should be involved or which investigations should be performed, most developed countries would agree a minimum of the following^{58,60,65 66}.

- Immunological compatibility – ABO blood grouping and lymphocytotoxic crossmatching. Incompatibility no longer excludes transplantation in some centres, although currently the majority of transplant units in the United Kingdom would

not proceed in these circumstances.

- General health – to exclude co-morbidities that may increase the risk of major complications peri- and post-operatively. Risk reduction of disease transmission to the recipient (*e.g.* viral or malignancy).
- Renal function – to ensure that:
 - a. donor has adequate renal reserve to live with a solitary kidney, and
 - b. the recipient receives a well-functioning transplant.

Both recipient and donor criteria must be considered when assessing the risk/benefit balance.

2.1.2: Recipient issues

The principal issues governing the safe selection of recipients for living donor kidney transplants are:

- Co-morbidities – The transplant operation should have a high chance of success which clearly requires that the recipient should be medically fit for surgery and anaesthesia and be able to tolerate common complications of renal transplantation for example rejection, delayed graft function, hypotension or bleeding⁶⁷.

- Primary disease – There should be an acceptably low risk of recurrence of the primary disease such that the life expectancy of the donated kidney and the benefit that this will bring is considered good enough to balance the risk associated with its donation⁵³.
- Psychosocial – The mental state and personality of the recipient should be such that the donor can be reassured that the recipient will comply with the drug regimen and any necessary interventions post transplantation⁶⁸.

The level of balance of risk and benefit is difficult to establish and may vary between individuals. Medical staff involved in dealing with the living donor pairing also need to display sensitivity in helping advise a balance between the patient's wishes (autonomy) with their own pragmatic assessment of benefit and risk (paternalism).

2.1.3: Donor issues

- General health - The donor should be suitably fit that they can withstand surgery with a low risk of complications such that organ donation does not present an unacceptable risk to them⁵³.
- Renal function – The renal function of the donor should be good enough to withstand the removal of a single kidney such that they do not develop renal failure following donation⁵³.
- Voluntarism to donate – The decision to donate must be given freely and without

coercion. Particularly under United Kingdom Legislation it is unlawful for the donor to receive payment for organ donation although there is a clause which permits reimbursement by the Local Health Authority or Trust of reasonable expenses which may include loss of earnings and travel⁶⁹.

The objectives of the study were to establish what the donor assessment, selection criteria and follow up practice were throughout all transplant units involved with living donor kidney transplantation in the United Kingdom, and to enable the identification of common practice and also highlight areas of disparity, allowing centres to examine and evaluate procedures.

Table 3 demonstrates basic clinical investigations recommended for living donor assessment⁷⁰

Table 3: Basic investigations for living donor assessment⁷⁰

History	General health: obesity, hypertension, diabetes Cardiovascular risk: past medical history, family history, smoking, obesity Respiratory risk: for anaesthetic: past medical history of asthma, etc, smoking Risk of renal disease: family history, particularly if disease in recipient is familial. Past history of renal infections, haematuria, renal calculi Psychiatric history
Examination	General Cardiovascular Respiratory Abdominal
Immunology screen	Blood group; HLA type; T & B cell FACS crossmatch
Haematology screen	Full blood count; coagulation studies
Biochemistry screen	Urea and electrolytes; Creatinine clearance; Liver function tests; Blood glucose
Urinalysis	Protein; blood; sugar Culture; sensitivity & microscopy
Cardiovascular	Serial blood pressure measurements; ECG
Virus screen	Hepatitis B and C; HIV; CMV; Epstein Barr Virus Syphilis; Toxoplasma
Radiology	Chest x-ray; Isotope GFR; Renal ultrasound; Angiogram/Spiral CT/MRA

2.2: Materials and methods

All living donor transplant centres in the UK were contacted and requested to complete a postal questionnaire at two time points - 1999 and 2002.

- Questionnaire 1 (1999) focused on clinical investigations and organisational structure (Appendix 1).
- Questionnaire 2 (2002) explored structure, ethical issues and donor selection (Appendix 2).

In 2000 the British Transplantation Society/Renal Association issued Living Kidney Donor Assessment Guidelines to provide a standard for living donor transplantation across the UK⁵⁵. These guidelines comprehensively cover many aspects of the clinical issues arising in the assessment and selection of living kidney donors and have been enthusiastically adopted by the transplant community. Thus Questionnaire 2 was adapted to explore the more difficult ethical issues that arise and were not addressed in the guideline publication.

2.2.1: Questionnaire 1

In 1999 there were 35 NHS Renal Transplant Units in the United Kingdom. The results of a telephone survey demonstrated that of the 35 centres, 30 performed live donor transplantation. One centre performed only paediatric transplants, with adult donors being

assessed and nephrectomy undertaken at another hospital (included in the research), therefore the paediatric centre was excluded. One further centre assessed live donors but had not undertaken a live donor transplant recently. Thus there were 31 centres included in the research.

Each unit was contacted by telephone to ascertain the appropriate person or persons to approach. The centres identified a transplant co-ordinator, nurse practitioner, physician or surgeon. The questionnaire was sent out with a stamped addressed return envelope, and a covering letter addressed specifically to the identified person. The forms were marked with a unique identity number to facilitate reminder letters if required. Respondents were assured all information would be treated in confidence and any report would maintain anonymity.

2.2.2: Questionnaire 2

In 2002 the number of renal transplant units performing living donor transplants had decreased to 25. All centres were contacted and an appropriate individual identified. A structured questionnaire was sent following the same principles as Questionnaire 1.

2.2.3: Questionnaire design

A structured question survey was chosen, so that data would be comparable among respondents⁷¹, and the majority of questions were closed, with yes/no or option answers.

Five main rules about questionnaire design were followed⁷²:

1. Ask questions that are easy to understand and answer.
2. Give clear instructions.
3. Adopt a format that eases analysis.
4. Allow questions to flow to maintain interest.
5. Consider overall impressions.

2.2.4: Preliminary pilot studies informing questionnaire design

Questionnaire 1 was piloted with 3 transplant co-ordinators and 3 transplant surgeons within the local team. A specialist in research and questionnaire design was also consulted. The feedback resulted in changes in wording of questions to improve understanding, modifying of option answers to increase clinical choice and change in the font and characters to improve overall impression.

Questionnaire 2 was piloted with 2 transplant co-ordinators and 3 transplant surgeons within the local team and similar minor adaptations were made to improve overall comprehension and to aid ease of subsequent analysis and interpretation.

The number of personnel involved in the pilot study was restricted due to the specialised nature of the subject and the number of qualified individuals within the UK to complete the questionnaire.

2.3: Results

2.3.1: Questionnaire 1 (1999)

2.3.2: Response rates and personnel involved in completing questionnaires

Twenty-nine of the 31 questionnaires sent were returned (94%). These centres had performed 1474 deceased donor renal transplants (98 per cent of the total for the UK and Ireland) and 150 live donor transplants (91 per cent of the total) of which nine were living unrelated transplants performed by seven centres. The questionnaire was completed by the transplant coordinator responsible for living donor transplants alone in 17 centres, in consultation with a transplant surgeon in four centres, by a renal physician in six centres, by a transplant surgeon in one centre and by a transplant surgeon and physician together in one centre.

2.3.3: Organisation and management of living kidney donor assessment

The organisation of live donor assessment was examined. It was established that 19 centres already had an established protocol, four were in the process of devising a

protocol and six had no protocol. The assessment of live donors was led by a transplant surgeon in eight centres, renal physician in ten, transplant coordinator in one, transplant coordinator and renal physician in two, and in eight the responsible person was not identified. A designated transplant coordinator/nurse practitioner was employed by 20 centres to manage live donor transplantation.

2.3.4: Arrangements for donor / recipient assessment

Donor and recipient were seen separately in all centres and were also interviewed together in 25 of the centres. Assessment by a psychiatrist or psychologist was routine for live related donors in five centres and for unrelated donors in six centres, and was a referral option in 13 centres for both live related and unrelated donors.

2.3.5: The intended recipient and the deceased donor waiting list

Recipients were removed from the transplant waiting list when donor assessment was complete in four centres, on the date of operation in 17 centres, after discussion with recipient and donor in three centres and four centres had no defined policy; there was one non-respondent. Twenty centres did not have an agreed time period between initial assessment and date of operation. A period of 3 months was suggested by four centres and 6 months by five.

2.3.6: Donor Investigations

Baseline investigations concerning the general fitness of the donor included full blood count, serum urea, creatinine and electrolyte estimation, liver function tests, chest radiography, electrocardiography and urinalysis; these tests were performed by all centres. Serum levels of calcium and phosphate were measured in 28 centres, uric acid in 20, thyroid function was determined in three, lipid profile in two and erythrocyte sedimentation rate in one centre.

Investigations relating to diabetes, hypertension, infection screening, renal function, renal tract anatomy and histocompatibility are summarized in Table 4. Other investigations reported were exercise tolerance test (four centres), cervical smear for female donors (one) and bladder ultrasonography for older male donors (one).

Table 4 – Number of centres routinely performing specified donor investigations

	No. of centres routinely performing investigation (n = 29)
Blood glucose	
Random blood glucose	27
Fasting blood glucose	9
Blood pressure	
Erect and supine blood pressure	23
Serial blood pressure	7
Ambulatory blood pressure	2
Infection screen	
Hepatitis A	1
Hepatitis B	29
Hepatitis C	29
Human immunodeficiency virus	29
Cytomegalovirus	29
Syphilis serology	15
Epstein–Barr virus	6
Renal function	
24-h urine for protein and creatinine clearance	23
Isotope glomerular filtration rate	24
Renal tract anatomy	
Angiography	28
Spiral computed tomography	1
Renal ultrasonography	23
Intravenous pyelography	14
Histocompatibility	
Tissue typing	29
Lymphocytotoxic cross-match	29
Flow cytometric cross-match	21

Number of centres (29) performing investigations relating to diabetes, hypertension, infection screening, renal function, renal tract anatomy and histocompatibility

2.3.7: Hypertension

Defined values for hypertension as an exclusion criterion had been established in 12 centres, but not in the majority. Using the World Health Organization criteria for hypertension⁷³ (mild hypertension: systolic pressure of 140-180 mmHg and/or diastolic pressure of 90-105 mmHg) and evidence of end-organ damage such as left ventricular failure or microalbuminuria the respondents were asked about an otherwise fit 40-year-old man. Responses are demonstrated in Table 5.

Table 5: Donor selection and hypertension

Scenario – 40 year old man, otherwise fit	Number of centres who would exclude as living kidney donor
Taking one anti-hypertensive drug (no end-organ damage)	9 centres
Mild hypertension (no medication; no end-organ damage)	13 centres
Borderline hypertension and evidence of end-organ damage	21 centres
Borderline hypertension and no-end-organ damage	9 centres

Number of centres who would exclude a donor in suggested scenarios relating to hypertension and evidence of end organ damage

2.3.8: Creatinine clearance

Given the scenario of a 50-year-old woman weighing 60 kg, levels of creatinine clearance below which exclusion from kidney donation should occur were considered to be 110 ml/min by two centres, 100 ml/min by four, 90 ml/min by four, 80 ml/min by seven and 70 ml/min by two. No response to this question was received from ten centres.

2.3.9: Other exclusion criteria

Diabetes mellitus: A fasting blood glucose concentration of more than 6 mmol/l was considered an exclusion criterion for organ donation by 15 centres, a relative contraindication by two centres and not an exclusion criterion by ten; two centres did not respond. A family history of diabetes was considered an exclusion criterion by four centres but not by 23, it was considered to be a relative contraindication by one centre and one centre did not respond.

Obesity: There were no exclusion criteria for obesity in ten centres. Others excluded donors whose body-weight exceeded their ideal body-weight by 15-20 per cent (8 centres), by 10-15 per cent (6 centres) and by less than 10 per cent (3 centres). One centre defined a body mass index of more than 40 or weight greater than 100 kg as exclusion criteria, while another excluded patients with a body mass index over 30.

Alcohol and smoking: A potential donor with a history of alcohol abuse would have been excluded by 15 centres but considered by 10 and 4 did not respond. Smokers of

more than 20 cigarettes per day would have been excluded as organ donors by 6 centres but considered by 20, 3 did not respond.

Age: The exclusion criteria used by centres with respect to minimum and maximum acceptable age for the donor are illustrated in Table 6.

Relationship: Child to parent donation would be considered in 25 centres, although most considered this appropriate only in exceptional circumstances, and this relationship would not have been considered in 4 centres.

Learning disabilities: Donors with mild learning disability would be accepted as donors by 11 centres and excluded as donors by a further 11. Seven centres either stated that individual assessment would be required or did not answer the question. Potential donors with moderate learning disability were excluded by 20 centres but would be accepted by 3 while 6 did not respond.

Women of childbearing age were considered as potential donors by all centres.

Table 6: Minimum and maximum donor age

	No. of centres (n= 29)
Minimum age (years)	
None	6
16	4
18	13
21	6
Maximum age (years)	
None	11
65	5
70	7
75	6

Minimum and maximum ages that centres recommend as limits for living donors in 29 centres

2.4: Results: Questionnaire 2 (2002)

In 2001 the number of living kidney donor transplants increased to 358 compared to 347 in 2000 in the UK⁴⁶. The 25 centres responding reflect all NHS live donor transplants performed in 2001.

The questionnaire was sent to the living donor transplant co-ordinator in all centres and completed by this transplant co-ordinator in 17 centres, in consultation with a surgeon in 5 centres, a physician in 2 centres and both surgeon and physician in one centre.

At the timepoint studied, 24 centres were assessing a total of 746 potential donors (range 5 – 80). One centre did not respond. Two centres performed a total of 20 laparoscopic donor nephrectomies in 2001 and 9 centres offered this option, the remaining 16 centres did not. Ten centres performed the donor nephrectomy and transplant simultaneously, nine centres sequentially and 5 depending on availability of theatres. One centre did not respond. Sixteen health boards reimbursed donor expenses and the remaining 9 received no health board reimbursement. Donor referral option to various health professionals is summarized in Table 7.

Table 7: Donor referral option – 25 centres

HealthCare Professional	Routine referral	Referral option available	No referral option
Independent Medical Assessor	9 (related)*		
Psychologist	4	9	12
Psychiatrist	3	9	13
Social Worker	4	8	13

* All unrelated donors required to be reviewed by an independent medical assessor according to the Human Organ Transplant Act 1989

Routine and referral options to selected health professionals for living donors in 25 centres

2.4.1: Relationship pairings

When asked which relationship pairings the centre would undertake, 5 centres had performed grandparent to grandchild live donor transplant, 15 would consider this in the future and 3 stated it was highly unlikely. Two centres did not respond. Twelve centres had performed child to parent, 7 would consider it in the future and 5 stated it was highly unlikely. One centre did not respond. No centre had performed grandchild to grandparent, 8 would consider in the future and 17 stated it was highly unlikely. Two centres did not respond.

2.4.2: Paired exchange and altruistic donation

Pending approval by ULTRA, 20 centres would consider paired exchange (an incompatible pair exchanging with another pair, where the donor and recipient from opposite pairs were compatible), 3 stated it was highly unlikely. Likewise, 16 centres would consider altruistic donation pending legislation and 7 would not. Two centres did not respond.

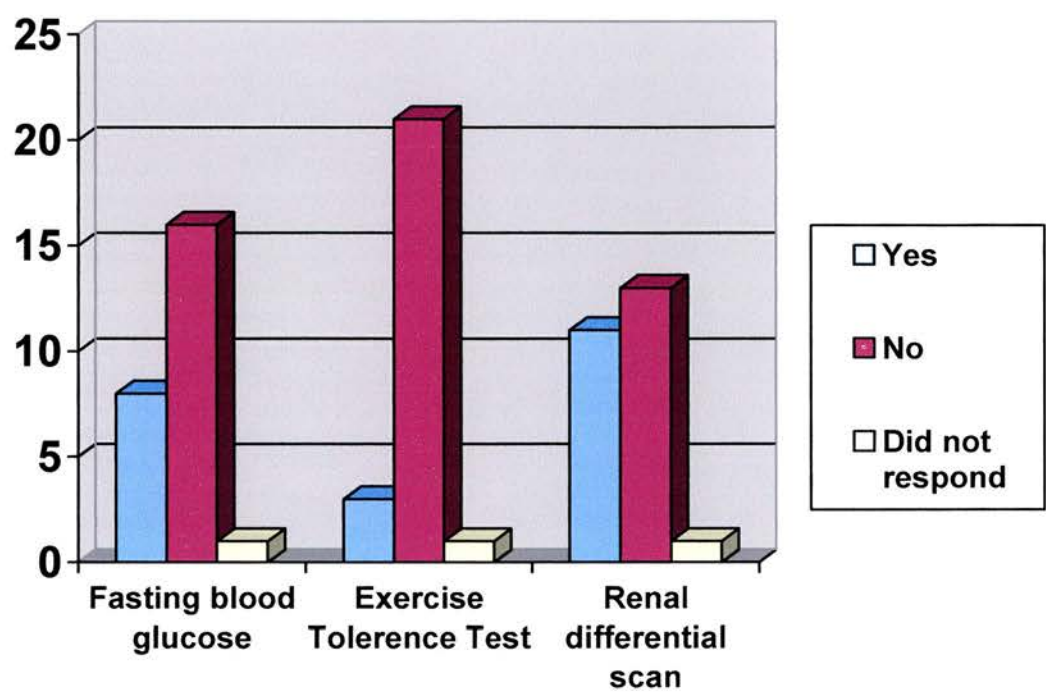
2.4.3: Further investigations

Investigations performed were reassessed in Questionnaire 2 because of publication of living donor guidelines by the British Transplant Society/Renal Association. These guidelines recommend the basic investigations for living donors. Centres were asked which additional investigations are routinely performed in their centre. Results are shown in Figure 4.

2.4.4: Response to scenario description

Three scenarios were described based on actual local referrals and the respondents requested to answer whether their centre would proceed with live donor transplantation in Table 8.

Figure 4: Additional donor investigations



Investigations requested on a routine basis for all potential donors (25 centres)

Table 8: Scenario response

<p>Scenario 1</p> <p><i>A 45 year old woman wishes to donate a kidney. She is married with 3 children – age 9, 11 and 15 years old. Her corrected isotope GFR is 72 mls/min, creatinine clearance 80mls/min and differential scan shows equal kidney function. All other investigations are satisfactory. She wishes to donate to her 15 year old son, who is pre-dialysis.</i></p> <p>Thirteen centres would proceed with donation, 9 centres would not and one was undecided. One centre did not respond. When asked if this same donor wished to donate to a friend, whom she has known since schooldays, only 6 centres would proceed, 16 would not, two centres were undecided and one did not respond.</p>
<p>Scenario 2</p> <p>A 40 year old woman wishes to donate to her 45 year old sister who has to travel 200 miles three times a week for haemodialysis. Due to medical history, the life expectancy of the recipient is 2-5 years. The potential donor does not have children, but does not rule out the possibility of a family in the future.</p> <p>In this scenario, 12 centres would proceed, 10 would not and two were undecided. One centre did not respond.</p>
<p>Scenario 3</p> <p>A 24 year old man wishes to donate to his 55 year old diabetic father. There are no other suitable family members, and his father has been on the transplant list for five years. Recently the recipient has been having problems with vascular access.</p> <p>Seventeen centres would proceed, 5 would not and two centres were undecided. One centre did not respond.</p>

Response of centres to potential living donor transplant scenarios with decision to proceed

2.5: Discussion

2.5.1: Questionnaire 1

This study surveyed the practice of live donor assessment by centres in the UK and Ireland which were responsible for 98 per cent of deceased donor and 91 per cent of live donor kidney transplants performed in 1997. Four centres did not perform living donor transplantation and only seven performed a living unrelated transplant in 1997. This raises the possibility that patients in some centres may not have had equal access to the potential benefits of living related and living unrelated transplantation. Those involved in purchasing renal healthcare for a population might reasonably ask that this modality of treatment be available to all willing and eligible patients. In addition the investigation of a donor and the definition of responsibility for that investigation would be considered very important, yet, at the time, ten of 29 centres involved in live donor transplantation did not have an agreed protocol. The absence of a protocol does not necessarily imply a lower standard of care or evaluation, however it is generally agreed that protocols do provide a useful structure for complex medical management and a safeguard against inadvertent omission or incorrect procedure.

The assessment of live donors is variably led by renal transplant surgeons and physicians, raising the question of who should be responsible for this role. It could be argued that the responsibility for the donor ultimately lies with the surgeon and that there is a potential conflict of interest for the renal physician, since it is the renal

recipient who derives clinical benefit from the procedure. All unrelated donors are required to be seen by an independent medical assessor. Although not a requirement under transplant legislation, independent medical assessors were used by ten centres to assess related donors. This perhaps reflects concern over the best representation of the donors' interests and the need to have a donors' advocate. All centres interview the donor separately from the recipient, implying recognition of the importance of ascertaining the family dynamics and providing an opportunity for donors to raise specific concerns which they may not wish to share with recipients. This raises the question of whether greater involvement of psychologists would aid in clarification of these issues.

There are no data indicating the optimal time to remove recipients from the deceased donor transplant waiting list once living donor transplant has been agreed. The conflict exists between the avoidance of surgery on a healthy individual who will derive no clear direct clinical benefit and the improved graft survival rate following live donor transplantation in comparison with deceased donor transplantation. In addition, a deceased donor organ which is not used because the recipient is transplanted from a living donor source can then be used to benefit another patient on the waiting list who may not have the option of living donor transplantation. Coupled with this issue is the question of whether it is useful to have a time lapse between initial donor assessment and subsequent transplantation. When a policy of leaving the recipient on the deceased donor transplant waiting list until the date of live donor transplantation is pursued in tandem with a long time lapse between donor assessment and transplantation, this will

inevitably reduce the availability of deceased donor organs for transplantation, since some recipients will be offered a transplant in the interval. In the present study, the majority of centres did not identify a rigid time period but there was a consensus that assessment should not be hurried. Furthermore, there are individuals who have varying degrees of commitment to donation and it may be important to consider the views of the donor and recipient before deciding on the most appropriate time for removal of the recipient from the transplant waiting list.

General investigations were performed by all centres but considerable variability was observed in the methods and thoroughness of infection screening, assessment of renal tract anatomy and renal function. The variation in practice of assessment of donors probably reflects the availability or expertise in different imaging modalities and local practices. No clear guidelines, based on sound clinical evidence, were available, to indicate which factors should be considered as exclusion criteria for live organ donation. This is reflected in the variability in response to creatinine clearance as an exclusion criterion and the relatively high rate (10 of 29 centres) of non-responders to this question. Similarly the WHO criteria for hypertension and the case scenario were considered very differently by centres with some laying greater emphasis on the presence of end organ damage and others on the presence of antihypertensive medication. Finally the variable response to the upper limit of weight or body mass index considered acceptable for living kidney donation was difficult to interpret and could have been explored in more detail by applying different questions. Specifically it

was not clear whether exclusion of obese individuals was on the basis of perceived technical difficulty, of perioperative risk or of subsequent cardiovascular disease risk.

The ethical dilemma of organ donation and informed consent from donors with learning difficulties is demonstrated by the low rate of acceptance (3 of 29) of donors with moderate learning disability in the present study. In the USA, Bia *et al* found that 46 per cent of centres do not have a policy regarding the use of donors with learning disabilities and 6 per cent accepted donors with severe intellectual impairment⁵⁸.

A further ethical dilemma relating to live donor transplantation arises with respect to the age of the donor. In the UK age 18 years is the legal age for provision of informed consent (Scotland, age 16 years)⁵³ however, in the present study six centres set no minimum age for organ donation. The most common age below which organ donation would not be considered was 18 years. At the other end of the scale, older donors have often been considered a greater operative risk and the functional results of grafts derived from older cadaveric donors are inferior to those from younger donors⁷⁴. Data from a large series of living donors suggest that graft survival is also dependent on donor age⁷⁵⁻⁷⁷. In the present study, 11 centres set no maximum age limit and a further six would consider live donation from donors over 70 years of age. In spite of a move to include older donors, only 3 per cent of all living kidney donors reported by the United Network of Organ Sharing were over 60 years of age⁷⁸.

Child to parent donation would be considered in 25 of the 29 centres, and all would consider women of childbearing potential as potential donors. Retrospective studies have

suggested that donor nephrectomy does not result in any increased risk of hypertension or hyperfiltration damage associated with subsequent pregnancy^{79,80}.

A recent study highlighted the concern that nephrectomy may increase the subsequent risk of developing nephropathy and advocated thorough evaluation of potential donors for diabetes and diabetic nephropathy⁸¹. In the present study, however, 10 centres did not consider a blood glucose concentration greater than 6 mmol/l to be an exclusion criterion for kidney donation. It is interesting to note that only 9 centres actually performed a fasting blood glucose measurement the remainder relying on random blood glucose as a screening tool.

2.5.2: Questionnaire 2

The number of potential donors assessed in 2002 (746) indicated a high level of interest in living kidney donation. However, when comparing this to the actual number of transplants performed, it can be estimated that approximately 50% of potential donors did not proceed. The reasons for potential donors failing to proceed to donation include blood group incompatibility, medical contra-indication and the recipient receiving a cadaveric transplant^{82,83}. With 20 centres willing to consider paired exchange, those blood group incompatible pairings would have the opportunity to 'swap' with another pairing. Similarly, the acceptance of marginal donors by some centres but not others may further affect transplant numbers. As with the first study, the time at which the recipient's name should be removed from the transplant waiting list remained variable

throughout the UK and no consensus had been reached over this dilemma. It may be argued that if a living donor is deemed acceptable to donate, then a deceased donor kidney should be utilised for those who do not have a suitable live donor. Conversely, the live donor avoids a major operation with associated risks.

The option of laparoscopic live kidney donation is rapidly increasing. A study in the USA suggests the number of live donor transplants increases when laparoscopic donation is offered alongside a formalized education programme⁸⁴. A systemic literature review in 2003 by Handschin concluded that laparoscopic donor nephrectomy would become the 'gold standard' in the near future⁸⁵. A lengthy discussion of the relative merits of laparoscopic versus open donor nephrectomy is beyond the scope of this thesis, but it is interesting that in the United States laparoscopic donation has become the standard of care without evidence of a randomized controlled trial comparing it with open nephrectomy. Whether patient power will exact the same change in clinical practice remains to be seen. Length of hospital stay and improved cosmetic results arising from laparoscopic kidney donation decrease disincentives to donation^{84;86}. In addition, the recipient outcome in a well established laparoscopic kidney donation programme is not compromised⁸⁷⁻⁹⁰.

The Human Organ Transplant Act 1989 allows payment of legitimate travel and loss of earning expenses for live donors with this responsibility devolved to the discretion of the recipient's Health Board⁶⁹. There appears to be an inequality of access to this financial assistance, and donors in regions where payments are not accessible may not proceed to

donation due to financial reasons. This issue requires to be addressed as kidney transplantation is the most cost-effective treatment for end stage renal disease^{41;91}.

Currently all unrelated donors require to be assessed by an Independent Medical Assessor for the purposes of Unrelated Live Transplant Regulatory Authority (ULTRA), to ensure that no payment or coercion of the donor is involved. There is no requirement for related donors to undergo such a review and it may be argued that blood relations experience pressure from within a family. Indeed, the benefits for a spouse or partner to donate probably outweigh those of a sibling living in another part of the country. It is still the minority of centres who routinely request an independent review for all donors.

The acceptance of certain relationships pairings relies on the views of the transplant centre approached. The balance of rights of the individual must be countered with the autonomy of the transplant surgeon in performing this type of operation. Whilst no centre has performed a grandchild to grandparent living donor transplant, 8 would consider in future. This is clearly a wider acceptance criteria than the 5 centres who state it would be very unlikely for a child to parent transplant to proceed.

The BTS/RA guidelines recommend the minimum acceptable renal function determined by inulin clearance for a 45 year old woman should be 74 mls/min and minimum creatinine clearance estimated by 24hour urine collection 93 mls/min. The acceptance by 13 centres for a woman with renal function below these limits for her son, and only 6 centres for her friend indicates the influence that relationship pairings have on the

decision making process. It may be argued that the rights of the donor should be respected and if she is deemed to be medically suitable the relationship with the recipient is irrelevant. However, in one of the other scenarios the life expectancy of the recipient, which may exclude his/her acceptance onto the cadaveric list due to the shortage of kidneys available for transplantation, did not prove to be a contra-indication to living donation in 10 centres. It may be suggested that by providing a personal 'resource' will compromise others waiting on the transplant list. The variation in acceptance demonstrates the difficult ethical decisions requiring to be made by transplant teams.

2.6: Conclusion

The British Transplantation Society and the Renal Association established a working party in 1999 to develop a national protocol to provide a consistent standard of care and assessment of live donors throughout the UK and these guidelines were published in 2000⁵⁵. However our second study has shown that there remains a variation in practice throughout the UK in selection of living kidney donors. Although many of the clinical aspects of assessment and selection were addressed the more challenging ethical issues require further debate and agreement. The acceptance of marginal donors depends on the individual centres, as does the relationship criteria. Some centres refer a donor who has been deemed unsuitable to other centres and this practice is likely to increase with more patient autonomy. Department of Health guidelines aim to enable patients the right to choose treatment options and the hospital that they receive treatment from by December

2005⁹². The option of laparoscopic donation is not available to all donors, and since this has the potential to increase the number of living donor transplants a referral option should be offered to those wishing this type of surgery. Overcoming barriers such as blood group incompatibility and positive lymphocytotoxic crossmatching with 'paired exchange' requires the forthcoming changes in the law following which the majority of centres would consider this option.

CHAPTER 3: QUALITY OF LIFE

3.1: Introduction

In 1946 the World Health Organisation defined health as ‘a state of complete physical, mental and social wellbeing, and not merely the absence of disease and infirmity’⁹³ and subsequently tools were developed to measure quality of life. Within the clinical field, the aim of such measurements has been to calculate changes in physical, functional, mental and social health in order to evaluate the human and financial costs and benefits of new programmes and interventions^{94;95}. By the end of the 1990s there were over 800 instruments to measure health-related quality of life⁹⁶. In general there are two types of quality of life assessment instruments - generic and disease-specific questionnaires. One of the most well known generic health profiles is the SF-36, which was developed from the Medical Outcomes Study in America⁹⁶. Tools such as this, and the World Health Organisation Quality of Life assessment instrument, provide a comparative scoring system for a range of individuals, cross culturally, and for a range of health conditions (including well) ^{97;98}. Disease specific questionnaires such as the end-stage renal disease questionnaire are only valuable when comparing treatment options for a select group of patients with identical disease processes⁹⁹.

Health economists usually prefer to use health indices to carry out cost-benefit analysis. A health indices is calculated by a single index with a range from 0 to 1.0 (0 being death and 1.0 being quality of life achieved with perfect health). A health indices score can then be multiplied with life expectancy to provide a QALY (Quality-adjusted Life

Years). This does not measure quality of life but gives a value to the outcome of treatment in terms of years spent in an improved health state⁹⁶.

The rapid development of transplantation over the past half century has resulted in major advances in the clinical field, with more promised in the future¹⁰⁰. It is important that the full range of cost and benefits to the individual recipient, his or her family and society in general are also considered¹⁰¹. In the case of living donation, the cost and benefit to the donor must also be measured. Many studies examining quality of life issues in living donor kidney transplantation have been retrospective, or have focused on cohorts of either donors or recipients in isolation as described in the examples shown in Table 9¹⁰²⁻¹¹⁴. In the United States, one study revealed that live kidney donors have similar or higher scores in all quality of life domains compared with the healthy US population and this observation was independent of the time since donation¹⁰⁹. Another European study demonstrated that recipients of both living donor and cadaveric transplants had mean quality of life scores within one standard deviation of the norm for healthy individuals¹¹⁵. Although such studies are useful, there is a lack of objective longitudinal data examining the relationship dynamics and quality of life of both donor and recipient as a pair through the process of living kidney donation and transplantation.

Relationships between donor, recipient and other family members provide a complex challenge. Feelings of guilt have more prominence in the recipients of transplants originating from living donors compared with cadaveric donors¹¹⁵. Individuals donating a kidney were less likely to say they would donate again (if it were possible) if they were

donating to a person who was not a close blood relative or if the recipient of their kidney had died in the first year after transplantation¹⁰⁹. Many of the quality of life studies have been performed in Europe, the USA and Australia, where payment for organs are illegal. A study by Zargooshi in Iran of 300 living kidney donor ‘vendors’ reported a negative effect on the majority of donors, with 85% saying they would definitely not vend again and the donors had significantly lower quality of life scores post donation compared to controls¹¹⁴

The lack of good quality and objective data concerning quality of life outcomes for living kidney donors and transplant recipients means that it is difficult for health care professionals to provide advice to individuals considering kidney donation other than in the context of clinical measures such as graft survival and operative risk. The present study was designed specifically to investigate the effect of donating or receiving a kidney among donor and recipient pairings on their quality of life and relationship dynamics over time.

Table 9: Quality of Life studies ¹⁰²⁻¹¹⁴

Author /Country	Number subjects	Type of study
C Cabrer; Spain	22	Donor - retrospective
Cetingok M; USA	293	Recipient - prospective
Christenson; USA	95	Recipient - prospective
de Graaf Olson W; USA	118	Donor - retrospective
Giessing M; Germany	106	Donor - retrospective
Griva K; UK	347	Recipient – retrospective
Isotoni S; Japan	69	Donor- retrospective
Johnson EM; USA	524	Donor - retrospective
Luk W; Hong Kong	31	Recipient - retrospective
Russell JD; Canada	27	Recipient – prospective
Siegal B; USA	3676	Recipient – retrospective
Smith GC; Australia	48	Donor - prospective
Zargooshi J; Iran	307	Donor - retrospective

3.1.2: Measuring Quality of Life – the World Health Organisation Group

A common definition for quality of life has yet to be achieved¹¹⁶. As it is a subjective concept, and tools developed have to be used in a variety of cross cultural settings, the emphasis has to be on what is important for each individual¹¹⁷. The World Health Organisation Quality of Life group (WHOQOL) define quality of life as ‘an individual’s perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns’¹¹⁸.

The subsequent development of the World Health Organisation Quality of Life Assessment Questionnaire (WHOQOL -100) was simultaneously developed in 15 international field centres so the questionnaire would be applicable cross-culturally¹¹⁸. Following the 15 centre pilot 100 items were selected for inclusion in the assessment. (Table 10)

The WHOQOL Bref is a shortened form of the WHOQOL 100 and discriminates between ‘well’ and ‘ill’ subjects¹¹⁸. This was felt to be particularly important as many quality of life questionnaires are designed to assess the impact of illness on a population. As this study compared ‘healthy’ donors and patients with end-stage renal failure the WHOQOL Bref was selected. Data were also available to compare an age-matched well population in the United Kingdom and worldwide¹¹⁹. Twenty-six questions produce

scores for four domains; physical, psychological, social and environmental related to quality of life.

Table 10: WHOQOL-BREF domains of quality of life

Domain	Facets incorporated within domains
1 Physical health	Pain and discomfort Sleep and rest Energy and fatigue Mobility Activities of daily living Dependence on medicinal substances and medical aids Work capacity
2 Psychological	Positive feeling Thinking, learning, memory and concentration Self-esteem Bodily image and appearance Negative feelings Spirituality/religion/personal beliefs
Social relationships	Personal relationships Social support Sexual activity
Environment	Freedom, physical safety and security Home environment Financial resources Health and social care: accessibility and quality Opportunities for acquiring new information and skills Participation in and opportunities for recreation and leisure activity Physical environment (pollution/noise/traffic/climate) Transport

The 24 facets (grouped into 4 domains) regarded by the World Health Organisation Quality of Life group as important in assessing overall quality of life and general health¹¹⁸

3.2: Methods and materials

This prospective, longitudinal study was undertaken between January 2000 and January 2004 in the transplant units of the Royal Infirmary, Edinburgh and Addenbrooke's Hospital, Cambridge. Both centres had similar policies regarding donor and recipient selection, pre-operative assessment and perioperative care. During the course of the study all donor nephrectomies were performed using an open technique with or without resection of the twelfth rib. Only adult subjects (>18years) were invited to participate as agreed with the local ethical approval committees. Both donor and recipient were asked to complete two questionnaires each at three time points: before; six weeks after and one year after the live donor transplant. The questionnaires included the World Health Organisation Quality of Life Bref (WHOQOL) and an additional questionnaire examining relationship issues and concerns related to the procedure (Appendix 4-6).

The additional questionnaires were designed using a 10cm linear-analogue scale with a member of the WHOQOL group (MJP) assisting in the development of the questions. The respondents were asked to state their response from minimum to maximum views on the scale. The recipients completed the same questionnaire at the same time points. The donor pre and post-operative questionnaire differed to encompass further social and economic issues experienced post donation.

The donor and recipient pairs were asked to complete the questionnaire separately, to avoid conflict of responses. The majority were completed during routine clinic visits, although due to geographical limitations a number were posted and returned. The questionnaires were numerically coded and anonymous, though demographic details were requested.

3.2.1: Statistical analysis

The WHOQOL-BREF produces a quality of life profile deriving the four domain scores¹²⁰. Higher scores denote higher quality of life. Data is analysed with an SPSS syntax file that recodes data and computes domain scores. Relationship data were transformed and analysed with SPSS, using Mann Whitney or Kruskal-Wallis H test as appropriate. Data are presented as boxplots, displaying the median score, interquartile range and error bars representing the range.

3.3: Results

3.3.1: Patient characteristics:

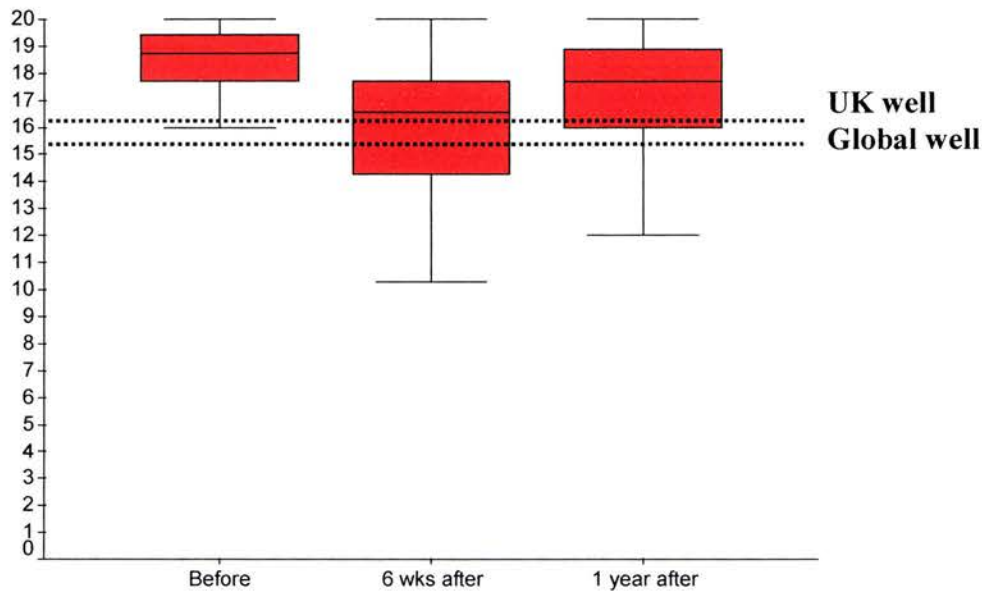
From January 2000 to December 2002 52 donor and recipient pairs consented to participate, 3 pairs declined. Twenty-three of the pairs were parent to adult child, 11 siblings, 16 spousal and 2 other non-related. Forty donors and 35 recipients completed the questionnaires at all 3 time points. Individuals who did not complete questionnaires at all time points were excluded from analysis. Treatment for renal failure for the 35 recipients included 13 undergoing haemodialysis; 14 peritoneal dialysis and 8 were transplanted before renal replacement therapy was necessary. All donors underwent open nephrectomy in this selected group. The mean age for the donors was 49 yrs (range 24-71 yrs), the recipients' mean age 37 yrs (range 19-54 yrs). Twenty-five donors were female and 15 donors male, 17 recipients were female and 18 male. One recipient died within one year of transplant and one recipient received two live donor transplants over the time period, the first having failed within one year. No donor suffered a major peri-operative complication.

3.3.2: Quality of life assessment

The WHOQOL scores are reported in the four domains – physical, psychological, social and environmental. The median physical scores for donors are summarised in Figure 5

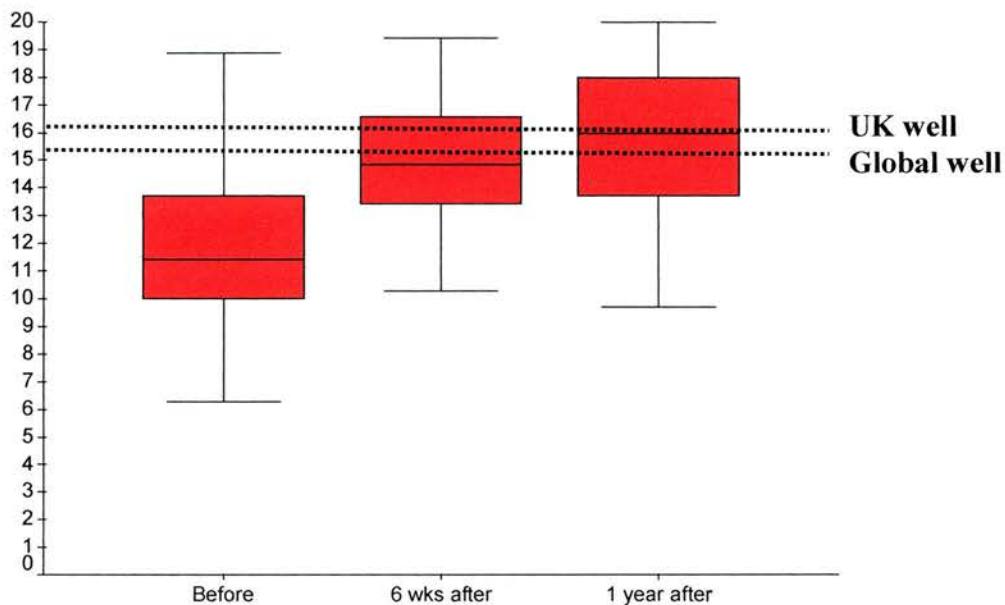
and further domain scores in Table 11. Recipients median physical score are demonstrated in Figure 6 and further domain scores in Table 12.

Figure 5: Donor physical quality of life domain



WHOQOL physical domain scores for adult donors of kidneys before, six weeks and 1 year after kidney donation. The boxplot displays the median score (middle line), the interquartile range and error bar range. The broken lines represent the median physical domain score an age and sex matched healthy UK and global population. There was a significant reduction in physical domain scores 6 weeks after donation ($\chi^2 = 17.2$; $df=2$ $p < 0.0001$ Kruskal-Wallis H test) with scores returning to pre donation levels by one year.

Figure 6: Recipient physical quality of life domain



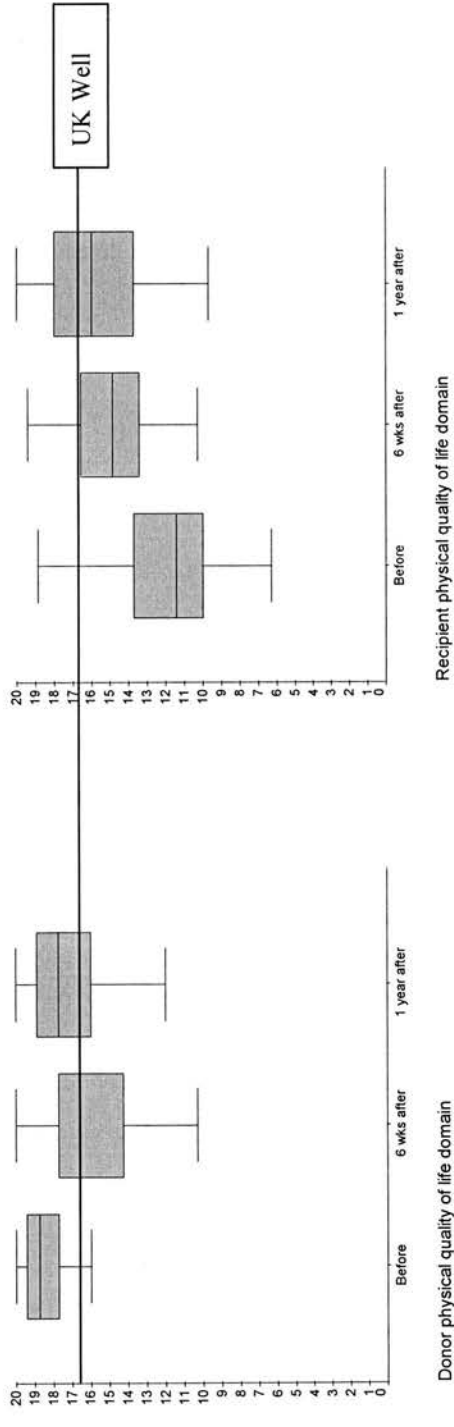
WHOQOL physical domain scores for adult recipients of kidneys before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. The broken lines represent the median physical domain score an age and sex matched healthy UK and global population. There was a significant increase in physical domain scores 6 weeks after transplantation ($\chi^2 = 26.6$; $df=2$ $p<0.0001$ Kruskal-Wallis H test.)

Table 12:WHOQOL recipient physical, psychological, social and environmental domain scores

QOL domain	Before n=35	6 wks n= 35	1 year n=35	UK well n=245	World well n=4472
Physical	11.4 (9.7-13.7)	14.9 (13.1-17.1)	16.0 (13.7-18.3)	16.4 (14.1-18.7)	15.4 (12.6-18.2)
Psychological	15.3 (12.7-16.0)	16.0 (14.7-16.7)	16.0 (15.3-16.7)	14.6 (12.0-17.5)	14.8 (12.1-17.5)
Social	16.0 (9.3-20.0)	16.0 (8.00-20.0)	16.0 (10.6-20.0)	15.4 (11.7-18.0)	14.9 (11.0-17.2)
Environment	16.0 (8.5-10.0)	16.5 (10.0-19.5)	16.0 (9.0-19.5)	14.7 (11.4-16.7)	14.1 (11.4-16.8)

WHOQOL physical, psychological, social and environmental domain scores for adult recipients of kidneys used for living-donor kidney transplantation, compared to UK and global healthy norms.

Figure 7: Physical quality of life domain – donor and recipient



QOL domain	Before	6 wks	1 year	UK well	World well
Donor	n=40	n= 40	n= 40	n=245	n=4472
physical domain	18.8 (17.6-19.4)	16.6* (14.2-17.7)	17.7 (16.0-18.9)	16.4 (14.1-18.7)	15.4 (12.6-18.2)
Recipient	11.4 (9.7-13.7)	14.9* (13.1-17.1)	16.0 (13.7-18.3)	16.4 (14.1-18.7)	15.4 (12.6-18.2)

There was a significant reduction in physical domain scores 6 weeks after donation ($\chi^2 = 17.2$; $df=2$ $p<0.0001$ Kruskal-Wallis H test) with scores returning to pre donation levels by one year. There was a significant increase in physical domain scores 6 weeks after transplantation ($\chi^2 = 26.6$; $df=2$ $p<0.0001$ Kruskal-Wallis H test.)

Within the physical domain the median score for the donor was significantly higher than the UK normative value for a healthy person ($p<0.001$). Six weeks after donation, the physical domain scores of donors reduced to normative levels however improved again at one year, although did not reach pre-donation levels. By contrast the median score for the recipient before transplantation was significantly lower than the UK normative value for a well person (11.4 pre-transplant vs 16.4 UK norm $p<0.01$). The physical domain quality of life measurement for the recipient significantly improved by 6 weeks and continued to improve such that by one year following living kidney transplantation it was not significantly different from the UK normative value for a well person.

Donor psychological domain scores before kidney donation were significantly greater than UK normative values for a well person ($p<0.012$). Although the donor psychological domain median decreased six weeks post donation, this score remained significantly higher than the UK population normative value ($p<0.001$). The recipient psychological domain scores before transplant were not significantly different from the UK normative value. However, following transplantation the psychological domain scores increased such that they were significantly higher than UK normative values at six weeks and one year ($p<0.01$). There was no significant difference between the donor and recipient psychological domain scores one year after kidney donation or transplantation respectively.

There were no significant changes in either the social or environmental domain scores of the donor or recipient groups before and after kidney donation or transplantation.

Individual cases to highlight within these results include the two donor and recipient pairs (Pair A where the recipient died within one year of transplant and Pair B where the graft failed due to rejection after eight months). All other transplants were successful and functioning at one year.

Pair A donor reported no difference in the physical, social or environmental domains, with a significantly lower psychological score at one year. The recipient reported an improvement in both physical and psychological domains at six weeks, sadly he was diagnosed with a malignancy six months post transplant and died shortly thereafter. Pair B's results are demonstrated in Table 13. Interestingly the recipient psychological domain returned to pre-transplant levels when the graft has failed and there was a decrease in both social and environmental scores, although the physical score did not return to pre-transplant levels.

Table 13: Pair B donor and recipient median scores

QOL domain	Donor			Recipient		
	Before	6 wks	1 year	Before	6 wks	1 year
Physical	18.3	17.1	16	6.3	16	9.7
Psychological	17.3	16.8	14.0	9.3	15.3	9.3
Social	18.7	16	16	14.7	17.3	13.3
Environment	17.5	17	14.5	11.5	13.1	9.1

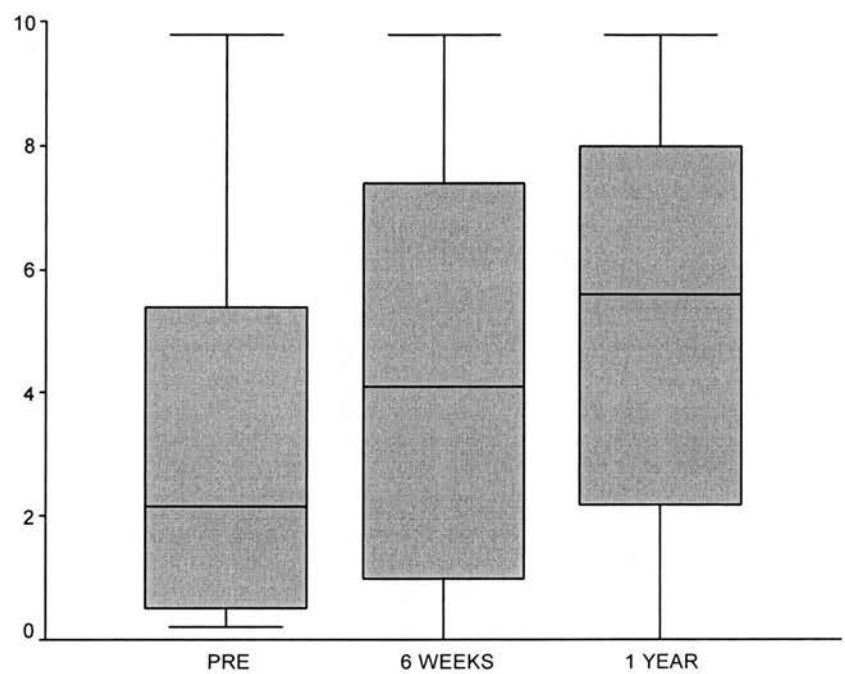
Quality of life scores for Pair B (graft failed at 8 months)

3.3.3: Relationship and social issues

The impact of living donor transplantation on the relationship of the pairing and family member and friends was addressed. The participants were asked to score on a linear analogue scale if the issue of live kidney donation had improved their relationship. The scale measured 10cm (0: not at all – 10: and extreme amount). The donor and recipient were also asked if the issue of live kidney donation had an adverse effect on relationship using the same scale. Both donor and recipient reported a significant improvement in their mutual relationship (Figures 8 & 9). When asked if the issue of live kidney donation had any adverse effect on their relationship, the donor median score was 0.8 pre donation, 1.7 six weeks post and 2.2 one year post. The recipient median score was lower: 0.6 pre transplant, 0.6 six weeks after and 0.7 one year later.

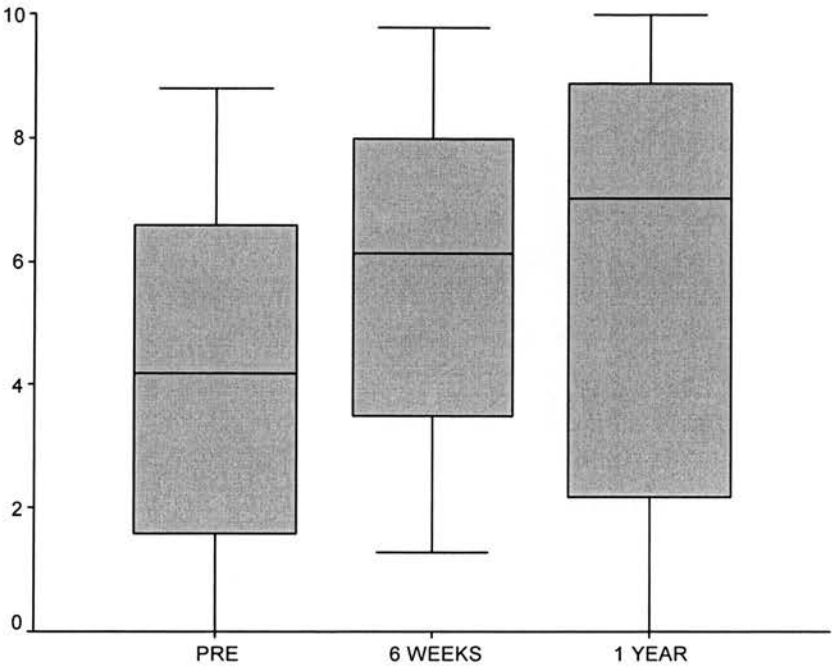
The recipients were asked to score their level of concern about the donor on the same 10cm scale (Figure 10). Initially the recipients expressed a high level of concern (median score 8.8) reducing at six weeks to 5.4. The donor was asked about their level of concern about their remaining kidney (Figure 11). Consistently the donors did not worry about their remaining kidney – 0.8 before the operation and six weeks after and increasing to 1.0 one year after. Post-operatively, when asked about scar discomfort experienced the median donor score was 2.0 at six weeks and 2.4 at one year. When asked, if it were possible, would they donate a kidney again, the donor median score was 8.9 at six weeks and 9.3 at one year.

Figure 8: Donor relationship with recipient



Donor relationship with recipient scores before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Donors report significant improvement in their relationship with the recipient following kidney donation ($p<0.009$)

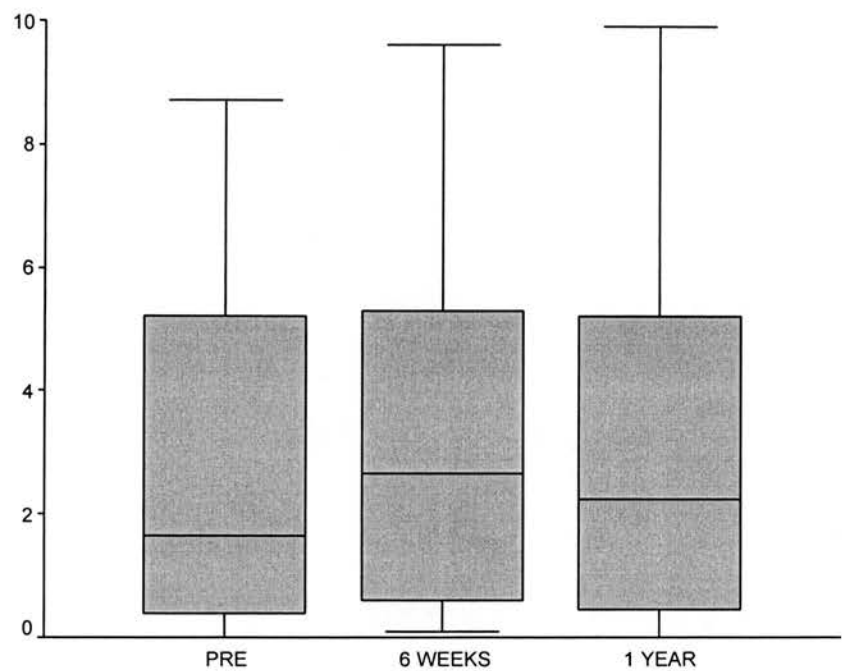
Figure 9
Recipient relationship with donor



Recipient relationship with donor scores before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Recipients report significant improvement in their relationship with the donor following kidney transplantation ($p<0.05$)

Figure 10

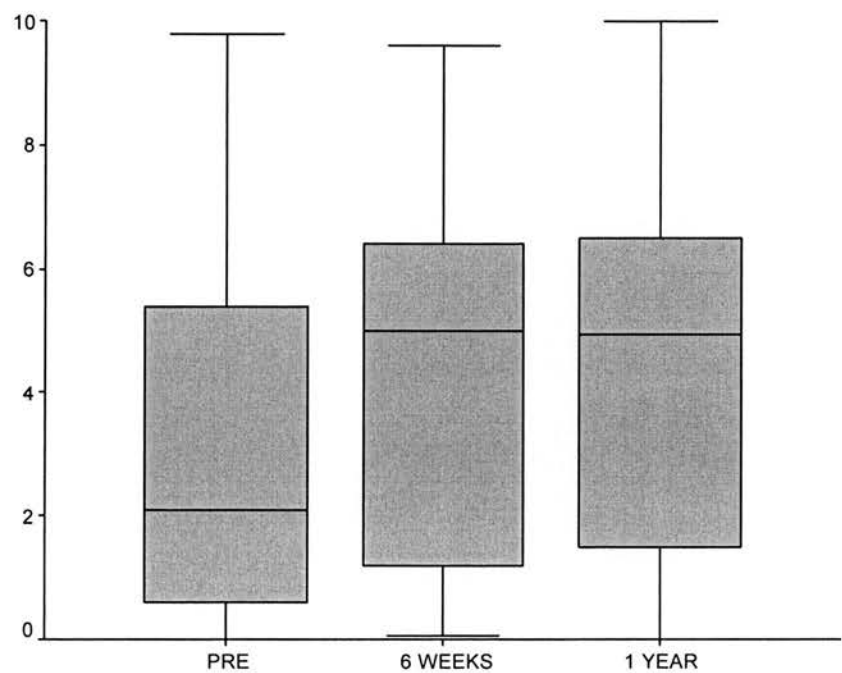
Donor relationship with family members



n/s

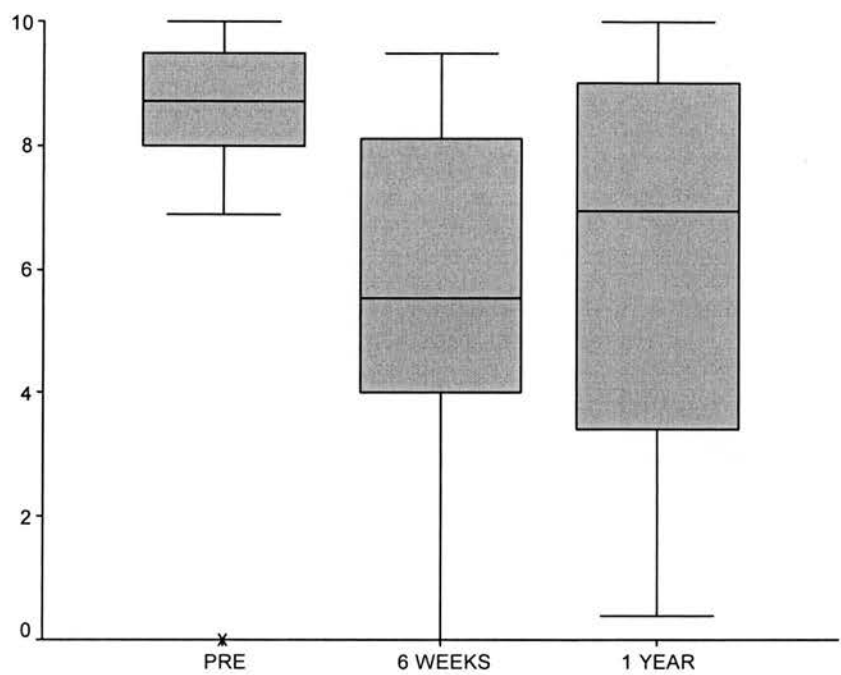
Donor relationship with family members scores before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Donors report no significant change in relationship with family members.

Figure 11: Recipient relationship with family members



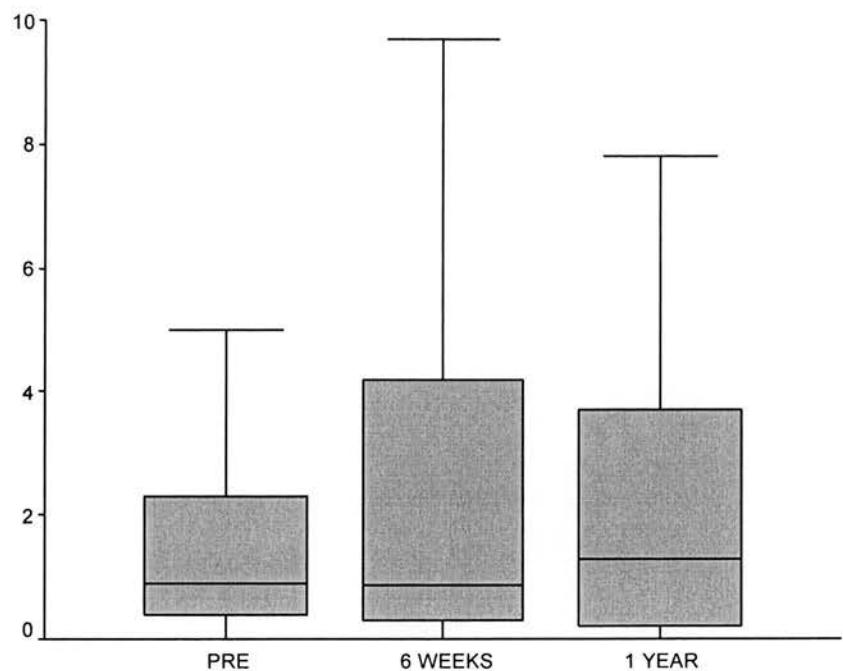
Recipient relationships with family members scores before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Recipients report significant improvement in relationships with other family members ($p<0.004$).

Figure 12: Recipients concerns about the donor



Recipient concerns about the welfare of the donor before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Recipients report significant reduction in concerns about the donor after living donor transplant($p<0.0001$).

Figure 13: Donor concern about remaining kidney



Donor concerns about their remaining kidney before, six weeks and 1 year after living donor kidney transplantation. The boxplot displays the median score (middle line), the interquartile range and error bar range. Donors do not have significant change in concerns about remaining kidney (n/s).

3.4: Discussion

This prospective, longitudinal study demonstrated that living donor kidney transplantation does not adversely affect the longer term physical, psychological and social wellbeing of donors and substantially improves many aspects of the lives of recipients. The intense medical evaluation of potential living kidney donors results in the selection of only healthy, motivated individuals. In addition, all live kidney donors are encouraged to achieve a high level of fitness prior to donation. In the light of this it is perhaps not surprising that the physical domain score for donors before operation is above the national norm, confirming results of previous studies^{105,106,109}. Likewise for the recipient, the physical improvement following transplantation confirms the benefit of this form of treatment^{28,121-123}.

The donors achieve a higher than normal psychological score pre-donation, decreasing at six weeks and one year, although remain at a level above the healthy population. It is possible that the selection of motivated individuals, coupled with the reassurance afforded by completion of the assessment process and the knowledge that they are fit to proceed, improves psychological well-being before donation. Similarly, for the recipient the knowledge that a transplant is imminent, may increase a sense of psychological well-being, in spite of the observed concerns that the recipient has for the safety of the donor.

No significant change in the social and environmental domain scores of either donor or recipient were observed. This is reassuring information for future donors that no adverse

effect is caused by donation. It was anticipated that for the recipient, freedom from dialysis might have resulted in improved social and environmental interaction. The lack of change may reflect the fact that a number of transplants were 'pre-emptive' (that is undertaken before dialysis was instituted) or the intensity of the follow up after transplantation. Benefits in social and environmental domains may become more apparent in the longer term, when the recipient does not require such intense follow-up.

Both the donor and recipient are informed in detail about the risks and benefits of living donor transplantation¹²⁴, with great emphasis on the risks to the donor undergoing a major operation. Thus recipient concerns about the donor are high before surgery, decreasing in response to successful outcome and donor recovery. The donors continue to have a low level of concern about living with a solitary kidney. The emphasis during assessment that donation will only proceed with minimum risk to the donor and maximum benefit to the recipient¹²⁴ may partly reassure donors, alongside the life-long follow-up commitment of the transplant team.

The impact of living kidney donation does not appear to have adverse effects on relationships either between donor and recipient or with other family members. The rigorous evaluation process may preclude pairs with the potential for family conflict. Donors consider that the act of donation improves relationships with the recipient and to a lesser extent with family and friends, whose support is vital in the post-operative period.

This study has demonstrated that living donor kidney transplantation does not adversely affect the lives of donors and substantially improves many aspects of the lives of recipients. Careful donor selection allows those with a higher than normal physical quality of life to donate without impairing their physical or psychological status. As a group, the issue of donation and transplantation does not have an adverse effect on relationships. The majority of living donors would donate again, providing reassuring information for potential donors.

CHAPTER 4: POST OPERATIVE COMPLICATIONS

4.1: Introduction

For the recipient of a living donor kidney transplant the clinical benefits are well recognized. As has been demonstrated transplantation versus dialysis provides improvement in quality of life, extends life expectancy and reduces co-morbid conditions^{121, 31;125}. Given that living donation is the only procedure where there is no obvious medical benefit to the donor it is incumbent on the medical profession to ensure that this is a safe procedure in which all possible risks are minimized. It is therefore important that the clinical implications of donating a kidney are adequately researched and monitored.

Various worldwide studies have addressed these issues, with more recent comparisons of the complications of laparoscopic versus open nephrectomy^{85;87;126;127}. The reporting of post-operative complication rates varies widely, possibly due to under reporting in large data registries compared to detailed casenote review. Many case series of living kidney donors are published on the premise that this is a safe and effective procedure and while this may be true the very premise that it is safe may introduce an inherent bias leading to a relative under-reporting of complications. Coupled with this is use of publications as advertisements for commercially driven medical care delivery. Publication of a large series with no mortality and low morbidity is a powerful

advertisement to both insurers and clients in countries that operate on a health insurance cost recovery basis rather than a nationally funded health care system such as our own. Nevertheless, large series based on registry data do report low death rates following living kidney donation and the reported death rates range from 0.03% – 0.06%¹²⁸. In these series the reported causes of death are predominantly pulmonary embolus and cardiac events^{128;129}. In a summary of perioperative complication rates for living donor nephrectomy for a large number of single centre studies the mean overall complication rate was 32% and the major peri-operative complication rate was 4.4%¹³⁰. Minor complications have been estimated between 8- 48% with 1.8% patients suffering from major complications¹²⁸. The spectrum of complications reported in the literature following living kidney donation is broad with some complications being what would be considered general complications of anaesthesia and the perioperative period and other clearly being related specifically to the procedure of living kidney donation^{128;131;132}

Rigorous donor assessment ensures that only healthy individuals with two well-functioning kidneys proceed to donation, and previous studies have shown kidney donors have an increased life expectancy when compared with an age-matched population¹³³. Table 14 summarises a study looking at morbidity and mortality after living kidney donation in the USA from 1999-2001, comparing laparoscopic and open nephrectomies¹³². Rates for reoperation, complications and readmissions were slightly higher for laparoscopic nephrectomy, however <1.3% overall for both types of surgery.

The purpose of this study was to examine the precise nature and quantity of short term complications following living kidney donation in two UK centres with similar practice for living kidney donation.

Table 14: Complications following donor nephrectomy – Survey of US transplant centres 1999-2001

Complication	Open nephrectomy (5660) %	Laparoscopic hand assisted (2239) %	Full laparoscopic nephrectomy (2929) %
Re-operation	0.4	1.0	0.9
Complications not needing re-operation	0.3	1	0.8
Bleeding	0.15	0.18	0.45
Bowel obstruction	0.05	0.27	0.1
Bowel injury	-	0.1	0.14
Hernia	0.18	0.5	0.03
DVT/Pulmonary embolus	0.02	0.09	0.1
Pneumothorax	0.09	0.05	-
Prolonged ileus	-	0.05	0.06
Rhabdomyolysis	-	0.09	0.13
Readmission rate	0.6%		1.6%

*Retrospective survey of live donor nephrectomy complications in 171 transplant units
in the USA (73% response rate)*

4.2: Methods and materials

Peri-operative adverse events were documented in 95 consecutive live kidney donors undergoing open nephrectomy in Addenbrooke's Hospital Cambridge (37 donors) and the Royal Infirmary of Edinburgh (58 donors) between 1997 and 2001. Both centres followed similar protocols for the evaluation of potential live kidney donors, involving rigorous assessment of general health and kidney function. A significant difference in the management of donors was that Cambridge routinely prescribed prophylactic antibiotics at time of anaesthetic induction while Edinburgh did not. This allowed comparison of the effect of antibiotic prophylaxis on the frequency of infective complications in donors. In addition, the majority of Edinburgh donors received epidural pain control, whilst Cambridge donors did not. An open approach with or without resection of the 12th rib was used for all procedures in both centres.

Donor complications were defined and recorded in a standardised format using a proforma specifically designed for this study and based on detailed case note review. Wound infection criteria followed Scottish Intercollegiate Guideline Network recommendations¹³⁴. The influence on the complications of age, gender, body mass index, smoking status and transplant centre was assessed.

4.2.1: Statistical Analysis

Results are presented as actual numbers, percentages or medians and ranges as appropriate. Complication rates between different groups were compared using the Pearson 2-sided Chi squared test. Length of stay in patients related to the presence or absence of peri-operative complications was compared using the Mann Whitney-U test. Statistical analysis was performed using SPSS version 11 for Windows.

4.3: Results

4.3.1: Donor characteristics

Of the 95 donors studied, 45 were men and 50 women. The recipients of these kidneys were 57 men and 38 women. Seventy-four of the transplants were performed between related pairings and 21 were unrelated. Of the 74 related, 13 shared both haplotypes; 53 shared one haplotype and 8 did not share a haplotype. The median age at time of donation was 46 years (range 24 - 65 years). A left nephrectomy was performed in 58 cases, with 37 patients undergoing a right nephrectomy. Twenty-six (27 per cent) of patients were smokers at time of donation, 3 (3 per cent) had given up smoking within six months of the surgery and the remaining 66 (70 per cent) were non-smokers. The Body Mass Index was calculated in 79 of the 95 donors, of these 11 (14 per cent) were calculated to have a BMI ≥ 30 .

4.3.2: Peri-operative complications

All peri-operative complications were reported, however minor. Sixty-four patients (67 per cent) had one or more peri-operative complication. These are summarised in Table 15. Two major complications were noted; one peri-operative haemorrhage and one post-operative haemorrhage, both requiring red cell concentrate transfusions. No correlation was found between conditional variables such as smoking habit, body mass index >30, gender and age and complication rates. There were no deaths in the study population.

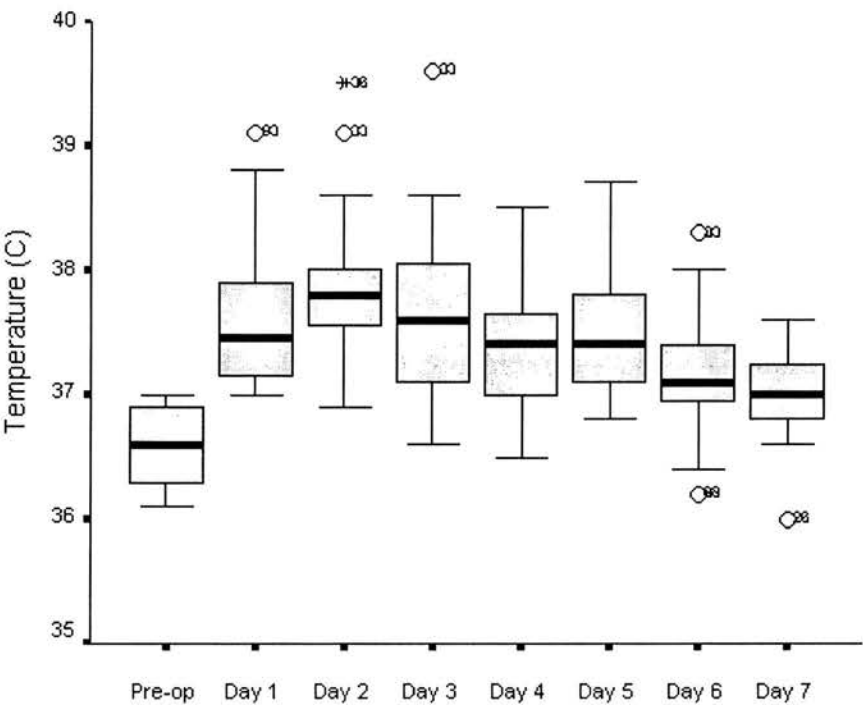
Post-operative pyrexia was recorded in the majority of patients within 48 hours of surgery (Figure 13). Seventy (74 per cent) of patients recorded a peak temperature $\geq 37.5^{\circ}\text{C}$, with 47 (50 per cent) recording a peak temperature $\geq 38.0^{\circ}\text{C}$. Within the latter group, only 25 (53 per cent) had a proven infection. Infective complications were found in 11 of 37 (30 per cent) donors from Cambridge compared with 27 of 58 (47 per cent) donors in Edinburgh (Chi squared=2.66, df=1, p=0.1).

Table 15: Peri-Operative Complications

Peri-operative Complications	Number	Per cent of Donors
Atelectasis	19	20
Chest infection	18	19
Urinary tract infection	12	13
Wound infection (superficial)	6	6
Wound infection (deep)	4	4
Wound dressing allergy/cellulitis	8	8
Peritoneum breached	7	7
Pneumothorax (no intervention required)	5	5
Epidural leak	2	2
Leg paraesthesia	2	2
Bleeding	2	2
Wound dehiscence	1	1
Pleural effusion	1	1
Sub-phrenic collection	1	1
Epidural catheter infection	1	1
Colitis	1	1
Cannula site infection	1	1
Wound haematoma	1	1

Peri-operative complications following open nephrectomy in 95 donors

Figure 14: Pre and postoperative temperature changes in donors following live kidney donation (n=95)



Temperature changes before and following open donor nephrectomy. The boxplot displays the median score (middle line), the interquartile range and error bar range, with outliers.

Constipation requiring medication occurred in 44 of 58 donors (76 per cent) who received epidural analgesia postoperatively compared with 22 of 37 donors (59 per cent) who received a combination of opiate and non-steroidal anti-inflammatory analgesia (Chi squared=2.9, df=1, p=0.09. No other centre differences were noted.

The median hospital stay was 5 days (range 3-8) for donors without post-operative complications and 6 days (range 3-12) for those with complications (p<0.01).

4.4: Discussion

Open nephrectomy for live kidney donation is associated with a low incidence of major complications however minor complications were significantly more common in the present study than previously reported^{128,131} This high complication rate may be explained by the detailed reporting of all aspects of post-operative care, including dressing allergies and asymptomatic atelectasis in this study.

The high rate of post operative pyrexia presumably reflects the metabolic response to surgery since microbiological cultures were positive in only a minority of patients with elevated body temperature. Postoperative pyrexia has been well recognised as a consequence of major surgery¹³⁵⁻¹³⁷ but not previously described in the context of living kidney donation. It has previously been shown that the presence of epidural analgesia does not influence the development of post operative pyrexia and this was also the case in this study¹³⁸.

There was no significant difference in the rates of proven infective complications between patients treated in Edinburgh and Cambridge in the absence and presence of prophylactic antibiotics respectively. This was not a primary outcome objective of this study and as such the study was underpowered to detect a difference in infection rates. While non-significant there was a trend for patients receiving antibiotic prophylaxis to have lower rates of infective complications and this unresolved question requires further study. Post-operative pyrexia is a common event occurring in the majority of donors and in the absence of positive microbiological cultures does not warrant intervention. The high rate of constipation in both centres did not appear to be significantly related to the type of post-operative analgesia.

The lack of correlation between smoking habit, BMI and age and perioperative complications could be attributed to the relatively small sample size but equally it may serve to demonstrate that the donor selection process eliminates the negative impact of adverse variables by excluding unhealthy individuals.

Potential live donors should be made aware of a relatively high incidence of minor complications in the early period following donor nephrectomy. Equally potential donors can be reassured that the incidence of serious complications is low. Data on the intermediate and long term outcome of live kidney donors in the UK is required to provide comprehensive information and supports the recommendation of the British Transplantation and Renal Society Guidelines that live kidney donors should undergo formal long term follow up.

CHAPTER 5: INSURANCE ISSUES IN LIVING KIDNEY DONATION

5.1: Introduction

The quantification of risk by insurance companies will affect assessment of kidney donors as potential customers. The long-term financial implications of donation have been documented as an area of concern for both donors and recipients¹³⁹. The majority of studies into insurance provision in this patient group are from the United States of America and have concluded that donors experienced no difficulties in gaining either life or medical insurance after donation. In 1986, Smith *et al.* found that 4.2% and 2.3% of donors admitted problems in obtaining life and health insurance respectively and that 98.3% noted no increase in premiums¹³⁹. The aim of this study was to ascertain the perspective of UK insurance companies to provision of insurance to live kidney donors since there are major differences in the organisation of health care in the UK and USA. This study formed part of a Special Studies Module for Sarah Clarke, 4th Year Medical Student at the University of Edinburgh.

5.2: Methods and materials

WHICH (consumer guide) and customer directories were used to determine the major life and health insurance providers in the UK. Thirty-two Life and 17 Medical Insurance companies were included. The Association of British Insurers was contacted to verify the number of people in the UK who have life insurance.

Separate questionnaires were designed for both health and life insurance providers and an appendix (detailing the assessment procedure and long-term physical consequences for donors) was attached. The Life Insurance questionnaire examined specific issues concerning cover should a donor die during or after surgery, and the acceptance of new customers pre and post donation. The Health Insurance questionnaire focussed on medical expenses and future cover for live kidney donors.

5.3: Results

5.3.1: Life Insurance

Of the 32 Life Insurance companies approached 14 replies were received (44%). These 14 companies insure approximately 6.5 million customers. Approximately 8.2 million people in the UK hold a life insurance policy and therefore results were obtained from companies supplying 79% of UK life insurance.

When questioned regarding their policy if an existing customer should die during kidney donation, 13/14 stated that they would pay the agreed life insurance sum. One company did not provide an answer as they had no experience of the situation and are currently deciding their position for future reference. No companies required to be informed by a customer of their intention to donate. Furthermore, 14/14 would accept new customers after previous kidney donation and would not charge an increased premium. When questioned if the time since donation was a factor taken into consideration when assessing new customers, 12/14 stated that it was. Insurers stated that for new customers the time since donation ceased to be relevant after 3 months (2/14), 6 months (7/14), 2 years (2/14) and one did not specify a time but considers customers “once full recovery is established”. In addition, 3/14 stated that the donor must “demonstrate a full recovery and be able to undertake all normal activities”. If a new customer were considering donation 3/14 would only accept the individual after donation and full recovery.

5.3.2: Health Insurance

Of the 17 Health insurance companies approached 7 replies were received (41%). The questionnaire was not completed by 1/7, as they “do not market new business”. Of the remaining six companies; 3/6 cover existing customers for kidney donation and of these, one covers donor investigation costs, donor operation, hospital costs and post-operative follow-up. Only one insurer covers donor operation and hospital costs alone and none pay donor travel expenses. Should an existing customer require a transplant 1/6 companies would pay recipient medical expenses; this company would also pay donor costs if the recipient and donor were both policyholders.

When questioned regarding sickness insurance, only 2/6 responders provide this product and neither of these cover donation in their policy, both would provide sickness insurance to a previous kidney donor.

All companies accept new customers after previous kidney donation although 2/6 stipulate that they exclude any problems arising from donation. When questioned regarding the premiums for previous kidney donors, 2/6 charge an increased rate and 4/6 do not.

When questioned if the time since donation was a factor taken into consideration when assessing new customers, 5/6 stated that it was. Time considerations are no longer thought to be relevant after 3 months by 1/6, 6 months by 1/6, 1 year by 1/6 and 2/6 feel that time considerations never cease to be relevant. One company admitted that the questionnaire highlighted inconsistencies in their approach and have implemented appropriate changes.

5.4: Discussion

Insurance companies providing life insurance to almost 80% of the life insurance policy holders in the UK would honour the terms of their agreement should An existing customer die as a consequence of live kidney donation. Results show that premiums are not raised; therefore kidney donation has no long-term financial implications regarding life insurance.

When considering new customers applying for insurance, there were significant inconsistencies among both life and health insurers in the amount of time post-donation that respondents considered relevant. Deaths associated with live kidney donation are rare but occur predominantly in the peri-operative period as do the great majority of complications and so these time considerations could be considered to be without scientific foundation. Similarly the demonstration of a “full recovery”, stipulated by certain insurers is an inexact pre-requisite and clear definition such as stable normal renal function or a return to work would be more helpful.

Kidney donation provides no medical benefit to the donor; however, the psychological, familial, emotional and social advantages are well documented¹⁴⁰ and described in earlier chapters of this work. It has been postulated that the increased life expectancy in donor populations’¹⁴¹ may be attributed to exclusion of concomitant illness by the rigorous assessment process and to increased self-esteem after donation⁸³. Considering this, the reluctance of certain health insurers to provide medical expenses for donors or

sickness benefit is disappointing. Given the documented improved survival of live kidney donor populations it is surprising that health insurance premiums charged by two companies are higher than for age matched non-kidney donors.

In Sweden, donors are compensated for loss of income by social security insurance, the recipients' county councils and the donors' employer¹⁴⁰. This resulted in 80% of donors receiving appropriate compensation in the 1990s. Whether a similar policy would improve live donor rates in the UK is uncertain and would be an interesting subject for a study.

Although kidney donation has no adverse financial sequelae regarding life insurance, it could be argued that life insurance premiums should actually be reduced post-donation. As not all UK insurers are included in this study, it would be prudent that prospective donors should contact their insurance provider to ascertain their position prior to kidney donation. Kidney donation has financial implications for health insurance. At the present time, the long-term effects of this are minimised due to the structure of the health service in the UK, however, future changes in health care provision may require a re-examination of the stance of health insurance providers on this issue. The financial security afforded by life and health insurance is of interest and importance to transplant clinicians, nephrologists and insurance companies but most of all to patients. The inconsistencies in many aspects of insurance provision to live kidney donors highlight the necessity to share information and strive for evidence-based practice from insurance providers.

CHAPTER 6: LONGER TERM FOLLOW-UP

6.1: Introduction

During the assessment of potential live kidney donors, the transplant team invest much time and effort ensuring each potential donor is medically assessed and fully informed of risks. It is the belief of many that this duty of care should persist following donation. A recent study examining donor's perception of their health after kidney donation included statements of concern about the lack of contact with the transplant unit and nurse coordinator following surgery¹⁰⁵. There are now increasing number of studies worldwide reporting modes of long term follow up implementation and retrospective review of the well being of living donors.

One of the initial and well cited studies was by Najarian *et al* in 1992 in the USA¹²⁹. Fifty seven donors who had donated >20years previously were compared to 65 siblings. In this study 32% of donors were taking anti-hypertensive drugs compared to 44% of the siblings and 23% donors had proteinuria compared to 22% of siblings. The study found no evidence of progressive renal deterioration in donors. In 1995 Kasiske *et al* analysed 48 studies with 3124 individuals who had undergone nephrectomy for donation, disease or trauma and 1703 controls¹⁴². Nephrectomy caused a decrease in glomerular filtration rate of 17 mls/min that improved with each 10 years of follow up by 1.4 mls/min. A small increase in systolic blood pressure (2.4 mmHg) continued to rise by 1.1 mmHg each decade and diastolic blood pressure was higher initially (3.1mmHg) but did not

continue to rise. A small progressive increase in proteinuria was also reported (76/mg/day/decade). A study in Pakistan evaluated the outcome of 736 donors in a dedicated live kidney donor follow up clinic and found that creatinine clearance fell to 87% of pre donation values at a mean time of 3 years (range 6 months to 18 years). Hypertension developed in 10% donors and 24% had proteinuria exceeding 150mg/24 hours¹⁴³. Grossman *et al* in Germany reported a review of 152 donors and found that 56% developed proteinuria (>150mg/day) although only 10% had albuminuria¹⁴⁴. In Sweden a study following 346 donors, hypertension was similar to an age-adjusted population, although approximately 10% of donors displayed proteinuria¹³³. No accelerated loss of renal function was found after donation, however 3 donors developed renal disease and 5 donors had a GFR below 30ml/min. This study recommended sparse but continued follow-up of living kidney donors.

There are specific problems which live kidney donors may encounter particularly in the early post-operative period which might not be obvious to health care professionals not involved in dealing with such patients on a regular basis. Several issues remain including how long should donors be followed up for and what form this follow up should take. National registries, both in the UK and in other European countries are being developed to obtain further information on the long-term outcome of donor nephrectomy¹⁴⁵.

6.1.1 Establishment of living donor follow up clinic

The concept of establishing a follow-up clinic for live kidney donors in 1999 was two-fold: firstly, to ensure that patients make a satisfactory recovery following donation and secondly, to obtain adequate information, collected prospectively, of the long-term risks of kidney donation for future potential donors.

The objectives of the clinic were:

- To provide continuity of care by the transplant team following donation
- To monitor renal function and blood pressure, and ongoing medical status
- To provide a setting where the long term welfare of a cohort of live kidney donors could be studied

The clinic was designed to be led by a transplant co-ordinator (qualified nurse) who had specific responsibility for live kidney donation, and was actively involved in the assessment of all live kidney donors. Permission to implement the clinic was granted by the hospital authorities who agreed to fund the clinic on a trial basis. In consultation with transplant surgeons and physicians, protocols were developed following standard guidelines for assessment and care in line with other existing protocols within the hospital.

There was concern that patients who had donated a kidney some years before might be concerned by receiving a letter inviting them to attend a clinic after several years without follow up. The purpose of the invitation and the establishment of recent guidelines were quoted as reasons for establishing the clinic. In the event the majority of patients were not concerned about being invited to re-attend the hospital. Where no

response was received and the recipient was known to the unit the enquiries were made with the recipient about whether further approaches should be made to initiate follow up with the donor.

6.1.2: Clinic organisation

Donors were requested to commence a urine collection 24 hours prior to attendance. They were asked specifically about problems with wound pain, and general problems that may be attributable to surgery, and were also given the opportunity to ask any questions which they may have regarding their donation or general health.

Following the appointment, any abnormal clinical results were discussed with an experienced physician. The results were reported to the donor's family practitioner and the donor by letter and on occasion the donor may be asked to re-attend the clinic for further assessment.

Any problems related to abnormal blood tests adverse events or deterioration of renal function were referred to a consultant physician for review and further management. In addition the nurse had access for referral to the transplant surgeons and physicians who were involved with the donor peri-operatively. In this way the clinic could be safely manned by an experienced nurse who had security in the knowledge that there was a clear line of referral for senior medical advice should this be necessary.

The necessity of a 24 hour urine collection required to be clarified, as it was inconvenient and a burden on the healthy donor. A further study was designed to ascertain the most accurate, minimally invasive and least labour intensive method of assessing renal function on an annual basis for living kidney donors.

6.2 Methods and materials

6.2.1 Follow up practice throughout the UK

To assess the provision of donor follow-up care in the United Kingdom the Transplant Units were contacted at two time periods (1999 and 2003). The follow-up questions formed part of the questionnaires requesting assessment information previously reported in Chapter1 of this thesis (Appendix 1 and Appendix 2). In both questionnaires the respondents were asked about personnel involved, length and regularity of follow up and investigations performed. Questionnaire 1 was sent to 31 centres in the UK in 1999 and Questionnaire 2 sent to 25 centres in 2003.

6.2.2: Nurse-led follow up clinic

Since the first living donor transplant in 1961, 150 live donor kidney transplants had been undertaken in the Transplant Unit in Edinburgh when the clinic was started in 1999. Where possible donors were traced and contacted initially by letter inviting them to attend the clinic. All family practitioners were informed of the clinic and forthcoming appointment. An audit was conducted to establish whether donors were satisfied with

arrangements for follow up and the structure of the clinic. Donors were asked questions concerning the convenience of clinic visits, personnel, flexibility and adequacy of follow-up.

6.2.3: Estimation of renal function

A study examining the strength of relationships between estimates of creatinine clearance and the Glomerular Filtration Rate (GFR) was instigated to establish the predictive power of standard formulae for estimating creatinine clearance from serum creatinine, and to provide evidence on the need for 24 hour urine collection. UK Transplant and the Kidney Pancreas Advisory Group kindly allowed access to the national database and data was analysed by Dr D Collett from UK Transplant.

Analysis was based on data from the National Transplant Database in the period from 1 November 2002 - July 2004 on living kidney donors in the UK. Data obtained from donors prior to transplantation and data from donors recorded at the one year follow up was used.

The strength of the relationship between creatinine clearance measured using 24 hour urine collection (CCI) and the GFR obtained using radioisotope techniques was explored. Since the GFR is not normally measured at the annual follow-up, pre-donation data for living donors was used to examine this relationship in a group of healthy individuals.

Serum creatinine was measured in $\mu\text{mol/l}$, creatinine clearance and GFR were measured in ml/min . All measures of creatinine clearance were corrected to give a value per 1.73 m^2 of body surface area. Body surface area was calculated using the Gehan formula¹⁴⁶, according to which the body surface area (BSA) is given by: $BSA = \text{weight}^{0.51456} \times \text{height}^{0.42246} \times 0.0235$; where the weight and height of the donor are measured in kg and cm, respectively.

From the measured serum creatinine level (SCr) the creatinine clearance was estimated using three different formulae: The Cockcroft-Gault formula¹⁴⁷; to Jelliffe¹⁴⁸; Jelliffe and Jelliffe¹²⁵ (Appendix C). Other formulae, such as the MDRD¹⁴⁹ equations and the expression due to Nankivell *et al*¹⁵⁰ were not used as these involve the values of variables that are not recorded on the National Transplant Database. In the pre-donation data set, the values of serum creatinine and creatinine clearance from urine collection were those measured on the date closest to that when the GFR was measured, and not more than 100 days pre-donation. In the post-donation data set, one year follow-up records for donors who were assessed between 10 and 16 months after donation were used. Data was recorded for 185 donors pre-donation and 99 donors post-donation, however there were only 34 donors in common in the two data sets. Table 16 shows the demographics of donors in each data set.

Table 16: Demographic characteristics of living kidney donors in each data set

	Pre-donation	Post-donation
Number of patients	185	99
Males	87 (47%)	42 (42%)
Females	98 (53%)	57 (58%)
Mean age (range)	46.4 (18-71)	49.7 (24-72)
Mean height (range)	169.3 (146-198)	168.4 (152-188)
Mean weight (range)	75.0 (43-112)	78.2 (47-116)

Demographics of donors pre and post donation for estimation of creatinine clearance

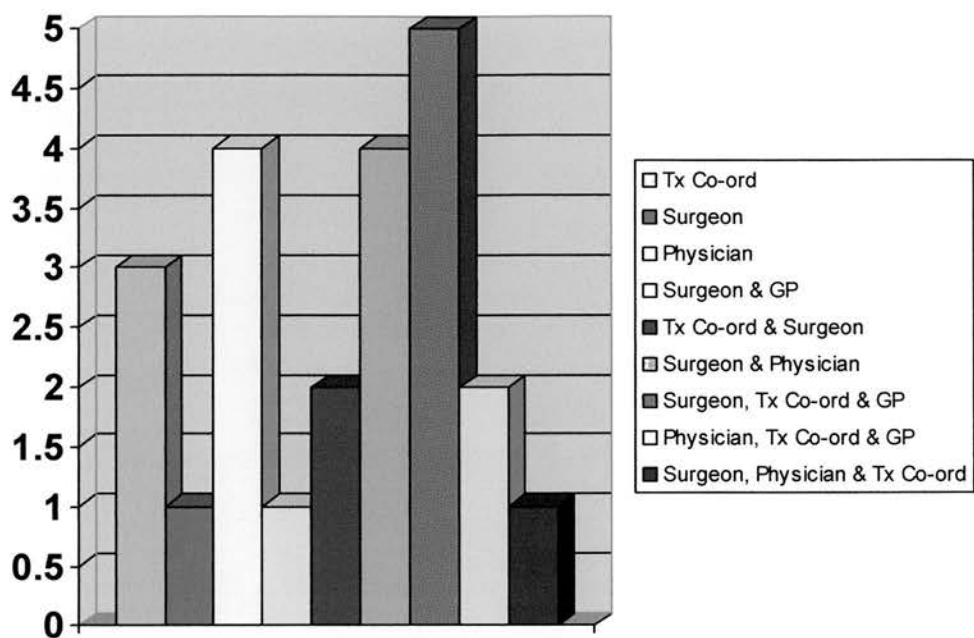
6.3: Results

6.3.1: Follow up practice throughout the UK

Twenty-nine responded to the follow up questions in 1999. When asked who arranged follow-up of live kidney donors the transplant unit took responsibility in 28 centres and in 11 this care was also coordinated jointly with the donors' general practitioners. One centre relied solely on the general practitioner for follow-up of the donor. The duration of follow-up of donors was reported as lifetime by 18 centres, 10 years by one centre, 5 years by two and 1 year by four. Following initial postoperative assessment no further follow-up was arranged by three centres, and there was one non-respondent. One year after organ donation, donors were seen every 6 months in one centre, annually by 19 centres and biannually by one. In the event of an unsuccessful transplant, counselling facilities were provided for the donor by 15 centres but were not available in 12 centres; no information was provided by two centres.

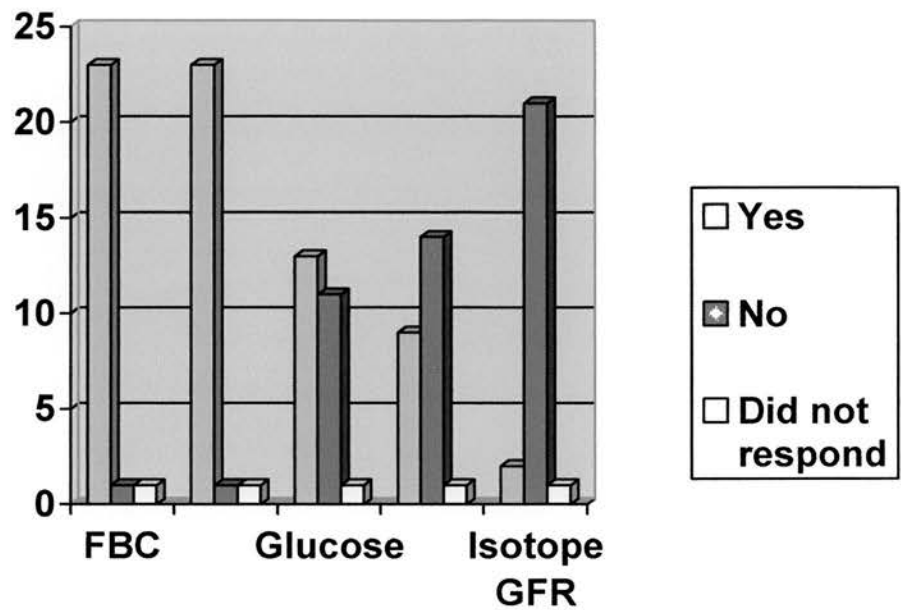
All 25 centres responded to questionnaire 2 in 2002. All 25 centres offered donor follow-up, one centre for less than one year, one centre for five years and 22 centres offered life-long follow-up. One centre did not respond. Personnel involved in follow-up are displayed in Figure 15. All follow-up centres measured blood pressure and blood chemistry, other investigations are displayed in Figure 16.

Figure 15: Personnel responsible for donor follow-up



Personnel responsible for donor follow-up in UK transplant centres in 2002(25 centres)

Figure 16: Donor follow-up investigations



Additional donor follow up investigations in UK transplant centres in 2002 – all centres measured blood pressure and blood chemistry (25 centres)

6.3.2: Nurse-led follow up clinic

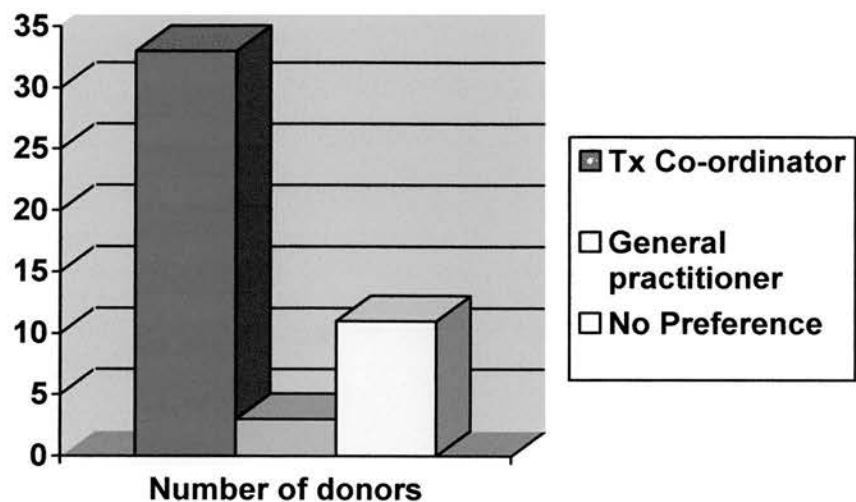
Contact information was obtained for 47 living donors who donated between the years 1986 and 2000. Fifty-nine appointments were booked (47 new; 12 return) and 12 (20%) donors did not attend. All the non-attendees were donors from the previous live donor programme, who were not aware of the follow-up programme.

For the 35 new donors who attended clinic, creatinine clearance, serum creatinine and urea were within acceptable limits for all donors. Three donors had raised random blood glucose levels, 8.1 mmol/l, 8.6 mmol/l and 9.5 mmol/l respectively (normal range 3.6-5.8mmol/l) and were referred to general practitioners for further management. Four donors had trace protein on dipstick urinalysis; however, on laboratory measurements protein was undetectable. One donor was attending a surgical clinic was ongoing wound problems and 2 additional donors were referred to the surgeons for review. Eight donors were found to be hypertensive at the clinic visit (170/90 -160/105 mmHg) and all were referred to general practitioners. Two donors were taking antihypertensive agents.

The audit questionnaire was completed by 47 donors (35 new; 12 return) requesting their views on the follow-up provided. Forty-three (91%) stated it was convenient to visit the hospital; forty-six (98%) felt there was enough flexibility with the appointment and 47 (100%) agreed it would provide adequate follow-up. Thirty-eight (81%) were satisfied with the follow-up they had received after kidney donation. When asked their preference with regard to who should undertake their follow up, thirty-three (70%)

stated a transplant co-ordinator with medical review, 3 (6%) would prefer general practitioner and 11 (23%) stated that they had no preference (Figure 17).

Figure 17: Personnel involved in follow up



Donor preference for personnel involved in follow-up (47 respondents)

Forty-two donors (89%) felt an annual review was sufficient, with the remaining 5 (11%) stating that it was not frequent enough. In situations where the donor found difficulty in attending due to the geographic distance from our clinic, their local transplant unit or general practitioner was contacted and arrangements were made for donor follow up using our model. In these circumstances the results of investigations were sent to the transplant unit for review.

6.3.3: Measurement of serum creatinine, creatinine and GFR

The mean values of serum creatinine and measures of creatinine clearance for living kidney donors in each data set (185 pre donation and 99 post donation), classified by age and sex are displayed in Table 17. The post-donation serum creatinine levels were substantially higher than those pre-donation, and the measure of creatinine clearance was correspondingly lower. There were highly significant differences between the mean values of SCr and CCl between the sexes in the pre-donation group ($p<0.01$). Post donation, the mean values of SCr and CCl differ significantly between the donor age groups, and the mean SCr values also differ between the sexes.

Table 17: Values of donor serum creatinine and measures of creatinine clearance

Age group	Sex	Pre-donation			Post-donation	
		SCr	CCl	GFR	SCr	CCl
18-34	Male	95.8	111.3	115.7	115.5	85.4
	Female	74.6	103.3	102.2	92.8	85.5
35-54	Male	99.9	109.6	110.7	124.0	81.6
	Female	78.3	97.0	106.4	101.1	73.6
55-72	Male	97.8	98.0	93.2	137.6	69.6
	Female	80.9	91.3	90.7	109.0	68.2

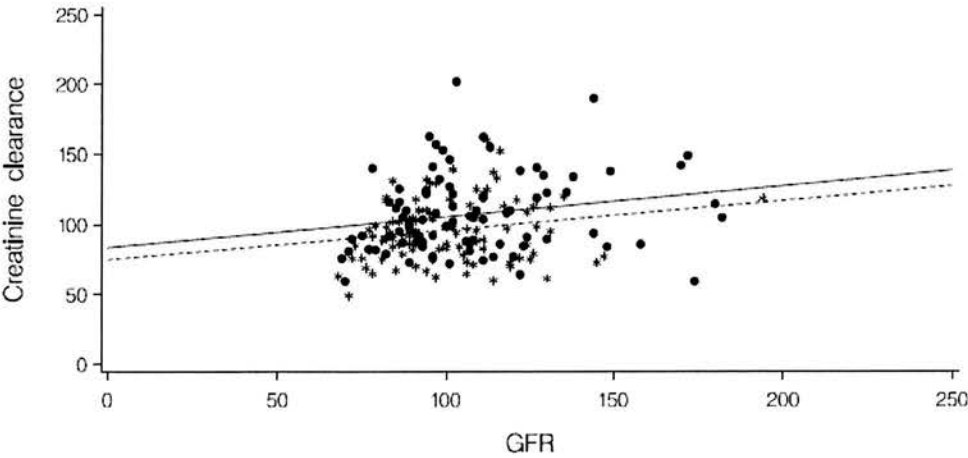
Mean values of serum creatinine and measures of creatinine clearance for living kidney donors in each data set, classified by age and sex: 185 donors pre donation and 99 post donation

6.3.4: Pre donation data

For this group of patients, the values of GFR, CCI and SCr are available for all but one of the patients in the database. Linear regression analysis shows that there was no evidence that the relationship between CCI and GFR was significantly different between the three age groups. However, there was evidence that the linear relationship was different for each gender ($p = 0.01$), in that the CCI was substantially higher for males than females. There was a significant linear relationship between CCI and GFR for each gender ($p = 0.008$), although only 8% of the variation in the values of CCI were explained by the differences in GFR values between the patients, after allowing for gender. Moreover, the slope of the straight line relationship is 0.22, which differed significantly from unity. This indicated that the GFR was substantially underestimated by CCI, for patients with higher GFR values, and overestimated at lower values. There was also evidence that the distribution of CCI values for patients with a particular GFR was not symmetric, as there was a tendency for the larger values of CCI to be more variable. These features are apparent in a plot of CCI against GFR, which is shown in Figure 18. The fitted regression line is included in Figure 18.

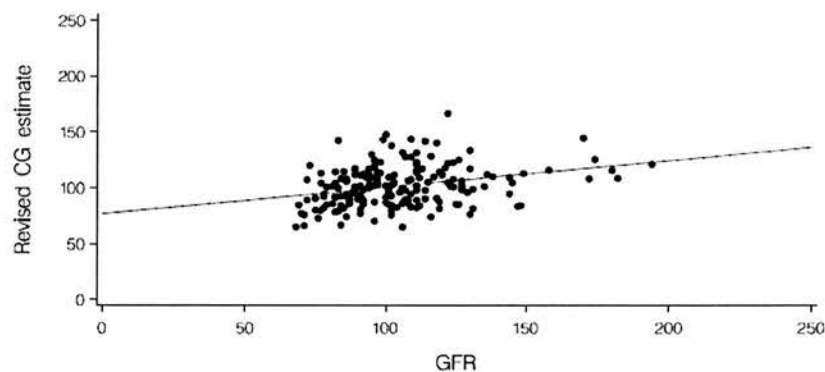
Traditionally, the Cockcroft-Gault formula is used to provide an estimate of creatinine clearance from the serum creatinine level, labelled CClcg. For this group of patients, there was a significant relationship between CClcg and GFR ($p < 0.001$), but the slope of 0.25 was significantly less than unity. Figure 19 shows a plot of the values of CClcg against the GFR, and the fitted regression line.

Figure 18: Plot of CCl against GFR for pre-donation patients of each sex (male — ● — female -- * --).



Pre donation plot of creatinine clearance against GFR for male and female patients, the GFR was substantially underestimated by CCl, for patients with higher GFR values, and overestimated at lower values

Figure 19: Revised Cockcroft-Gault estimate and GFR values pre-donation



Cockcroft-gault estimates against GFR in pre-donation figures. There was a significant relationship between CClcg and GFR ($p<0.001$)

Figure 19 shows less variability about the fitted linear relationship than in Figure 18, suggesting that CCl_{CG} is a better predictor of the GFR than CCl . Very similar plots were found when using the two estimates of creatinine clearance due to Jelliffe. The correlation between each of the two Jelliffe estimates of creatinine clearance and GFR is less than that for the Cockcroft-Gault estimate, indicating that for this type of patient, the Cockcroft-Gault expression has greater explanatory power.

The results described in this section strongly suggest that for potential live kidney donors, measurement of creatinine clearance through 24 hour urine collection does not provide additional information about GFR than can be obtained from the Cockcroft-Gault serum creatinine measurement.

6.3.5: Post donation

In the analysis of this group, there were only 10 of the 99 patients in the data set for whom the value of the GFR is available at follow up. For these patients, there was no significant relationship between values of CCl and GFR ($p = 0.91$), but there was a strong linear association between the values of CClcg and GFR post-donation ($p = 0.009$).

It was concluded that, as in the case for patients pre-donation, knowledge of the CCl value from urine collection does not provide any information about the GFR over and above the (limited) information from the Cockcroft-Gault estimate of creatinine clearance derived from serum creatinine. The data available encompass a very limited range of GFR values, from 49 to 67. This was because the GFR is only likely to be measured directly post-donation when there is some concern about the donor's renal function. Consequently, inferences drawn from this analysis are not necessarily applicable to individuals with higher GFR values.

6.4: Discussion

Previous live kidney donor follow-up studies have concluded that further information concerning the long-term renal function of those living with a solitary kidney should be obtained by large multi-centre studies or national registries¹⁴². The principal focus of live donor care has been on the assessment and perioperative care of the donor. It is now

time that a similar emphasis was placed on the long term outlook of these individuals. Many centres in this country and others did not have a structure for the follow up of live donors. Part of the reason for this is that there is little evidence upon which to base recommendations for follow up. Following guidelines that live donors should undergo follow up life long a clinic was initiated for this sole purpose. It may be that as data accumulate on the long-term postoperative outcomes of living kidney donation that the duration, frequency and nature of follow up can be revised. Until such evidence is available it will be necessary to audit outcomes of these patients through donor follow up clinics.

The high attendance rate in this study suggests that live kidney donors value the provision of long-term follow up, with acknowledgment of on-going care from the transplant team. The preliminary audit results confirm acceptability of a nurse-managed service. In addition attendees commented that they appreciated the flexibility of the appointment system. It is essential that donors who live outwith reasonable travelling distance to the transplant unit receive similar care to those attending the central unit and for this reason a follow-up proforma was established which is provided to family practitioners or referring renal units to facilitate this aim. With many transplant centres aiming to increase the number of live kidney donors, adequate resources should be made for follow-up. It is anticipated that one benefit of live donor follow up clinics is that it will enable improved quality of data that may be used to provide more accurate information for future live donors.

In 2000 the British Transplantation Society/Renal Association Living Donor Guidelines recommended the lifelong follow-up of all kidney donors and the United Kingdom Transplant database has prospectively collated data on living donors from 2002. Thus follow-up of living donors is now routine in the UK, although investigations performed vary across centres, as previously no clear guidelines have been issued with recommendation of appropriate interventional investigations required for this group. Donor attendance must be encouraged and lifestyle disruption should therefore be limited. The objective of creatinine clearance study was to balance the safety and accuracy of estimation of renal function with minimal inconvenience for this otherwise healthy cohort of people.

Neither CCl nor the estimate derived from the Cockcroft-Gault formula are particularly strongly associated with GFR in healthy patients. However, the information about this post-donation is somewhat limited, as the GFR is only measured in about 10% of patients at the one year follow-up. The main message from the analysis was that estimates of creatinine clearance derived from 24 hour urine collection, or estimates derived from the Cockcroft-Gault formula do not correlate well with GFR in living kidney donors.

If the GFR is not to be used to provide a value for creatinine clearance, the Cockcroft-Gault estimate derived from the serum creatinine level leads to a more precise estimate of creatinine clearance than the CCl value. There is little to be gained from requiring

patients to obtain 24 hour urine sample as part of the annual follow up process. However, it is recommended that a spot urine sample should be tested for proteinuria.

The model for live donation presented here may not suit all centres, particularly those where the geographic distance of the donors precludes their attendance at a central unit. It is hoped that the principles that have been established will provide a useful model for other centers wishing to establish similar clinics.

CHAPTER 7: CONCLUSION

7.1: Renal failure and transplantation

Developments in transplantation over the past half century have both addressed the problem of end stage organ failure for many patients and their families and also presented us with new challenges and ethical dilemmas. The replacement of an organ is a concept that was a vision in medieval times and is now accepted as a routine treatment. In a similar way we can anticipate the developments in the future with stem cell therapy and xenotransplantation as perhaps solving the problems of organ shortage but presenting us with a new set of complex ethical and moral issues.

The history of transplantation is a fascinating and well documented field. The pioneers of transplantation such as Sir Peter Medawar and Joseph Murray became Nobel prize winners for their work^{7,9}. Without the experimentation and ingenuity of these individuals in the 20th century, organ and tissue transplantation would not have reached the standard achieved today. Perhaps one of the most intriguing aspects of transplantation is the combination of technical, clinical and scientific knowledge required to allow progress and success. Sir Roy Calne commented that the whole attitude of the medical profession changed with the introduction of cyclosporine. Before that, he said, “transplantation was regarded as an enterprise for mad surgeons ignorant of immunology who really didn’t know what they were doing and who obtained unpredictable results”¹⁵¹. Fortunately surgeons such as Sir Roy Calne were far from ignorant of immunology and his

combined technical skill and research into immunosuppressive therapy resulted in transplantation moving from experimental stages to the preferred treatment option we know today.

Much work has also been done to develop 'bridges' to transplantation. Today many patients will view dialysis as a temporary life saving measure necessary until an organ becomes available. However the development of haemodialysis in the mid 1900s has proved to be as life saving as transplantation and is now available to a much larger group of patients. Unfortunately for those with end stage liver, cardiac and respiratory failure the therapeutic options are not so sustainable – thus deaths on these transplant waiting lists are higher in percentage. Improvements in treatment and a range of innovative support devices have still not removed the need for transplantation.

The cost of renal failure is not purely financial. The medical and social implications of end stage renal disease affect individuals from all spheres of life. Most kidney diseases are not self inflicted through abuse of drugs such as alcohol, smoking or other substances, and thus cannot be circumvented by public health education. Careful adherence to diet and medication can prolong native kidney function to a certain extent, although for many the requirement for renal replacement therapy is an inevitable reality. Our aim is to provide the best possible treatment for patients in these circumstances and combine clinical and social knowledge to ensure the benefits of a particular treatment outweighs the risks. In the reality of day to day clinical medicine this can be extremely difficult and for those working within transplantation each individual patient can appear

to challenge the knowledge and decision making ability of even the most experienced clinicians.

Research and evidence-based practice provide a strong framework to base decisions upon. We know far more now about the mechanics of organ rejection than even 20 years ago, yet there can still be the rare situation of an acute rejection in which the graft cannot be saved. The immunosuppressant agents available today for the most part can prevent such rejection, but must be balanced with the safety of the patient so they are not so immunocompromised that an overwhelming infection causes serious consequences. The shortage of organs has demanded that more marginal donors now proceed to donation and the recipient may be at more risk of receiving a poorly functioning graft that may expose them to foreign antigens. The opportunity of subsequent transplantation may be reduced due to this sensitization.

Clearly the best option for many of these patients with end stage renal failure is a transplant from a living donor, both from a clinical and social viewpoint. The focus of our study has been to ascertain that we can safely promote living donor transplantation within the United Kingdom. There will always be individual circumstances that present where we cannot anticipate the correct answer – but by building on this knowledge and experience we are in a stronger position to advise and set standards of acceptable practice.

7.2: Increasing Organ Donation in the UK

Countries such as Norway and the USA compensate for lower deceased donor rates with enthusiastic living donor programmes, whereas in Spain, with the highest organ donor rate in the world, living donor transplants feature to a lesser extent (Table 18). In certain parts of Asia where the concept of brain stem death is not accepted the transplant candidates rely solely on living donors, although this is slowly changing. This worldwide overview does suggest that live donation ‘fills the gap’, and reflects the fact that although clinically live donor transplants may be a good option for patients, the use of organs from deceased donors is preferable.

The ratio of living donor and deceased donor transplants in countries such as Norway and the USA should not be unrealistic targets for the UK. There are geographical and organisational similarities between Norway and Scotland, and although Scotland does maintain a reasonable living donor rate there are key operational differences that clearly

Table 18: Organ donation rates per million population worldwide 2004⁴⁴

Country	Living pmp	Deceased pmp	Non-Heartbeating pmp
France	3.5	21	0
Norway	20.7	19.6	0
Pakistan	15.1	0 (4 donors)	0
Spain	1.8	34.6	1.8
UK	8	12.3	1.5
USA	23.8	24.4	0

Comparison of organ donation rates per million population for living, heartbeating and non-heartbeating donors

do impact upon the number of transplants performed. In Norway the policy of not adding a patient's name to the transplant waiting list until live donation has been explored with all potential donors differs considerably from the UK. Donors are contacted directly by the nephrologists in Norway, whilst the UK operate a strict policy that the potential donor must initiate contact and drive the donation process. Would the UK be ready to adopt a more direct approach to family members?

The increase of living donor numbers in the USA is probably partly driven by economic considerations. Medicare will only pay 80% of dialysis costs – thus the financial impact on a family can be considerable¹⁵². In the UK all dialysis expenses are met by the NHS, indeed patients can actually be in a poorer financial position with a functioning transplant. This is due to the social security benefits system recognizing renal failure as long term sickness and benefits awarded accordingly. When a patient receives a transplant these benefits may be withdrawn. Similarly, prescription charges are waived for patients on dialysis however this waiver does not apply to immunosuppressants post transplant.

So if we examine the worldwide organ donation rates a clear picture emerges – those with higher deceased donor rates do not rely on living donation and vice versa. Within the UK we are attempting to increase both sources. Unfortunately the deceased organ donation rates are limited by a more fundamental lack of resources compared to other countries – the provision of intensive care beds in the UK is 0.8% of acute hospital beds

compared with 3-5% in other European countries and 10-12% in the USA¹⁵³. The number of families refusing to donate organs does vary in accordance with media reporting, but rarely drops below 30% in any region⁴⁶. Changes in the law in both England and Scotland will place greater emphasis on the wishes of the individual during their lifetime, though the support of families will still be required in practice if not in law.

7.3: Increasing living donation in the UK

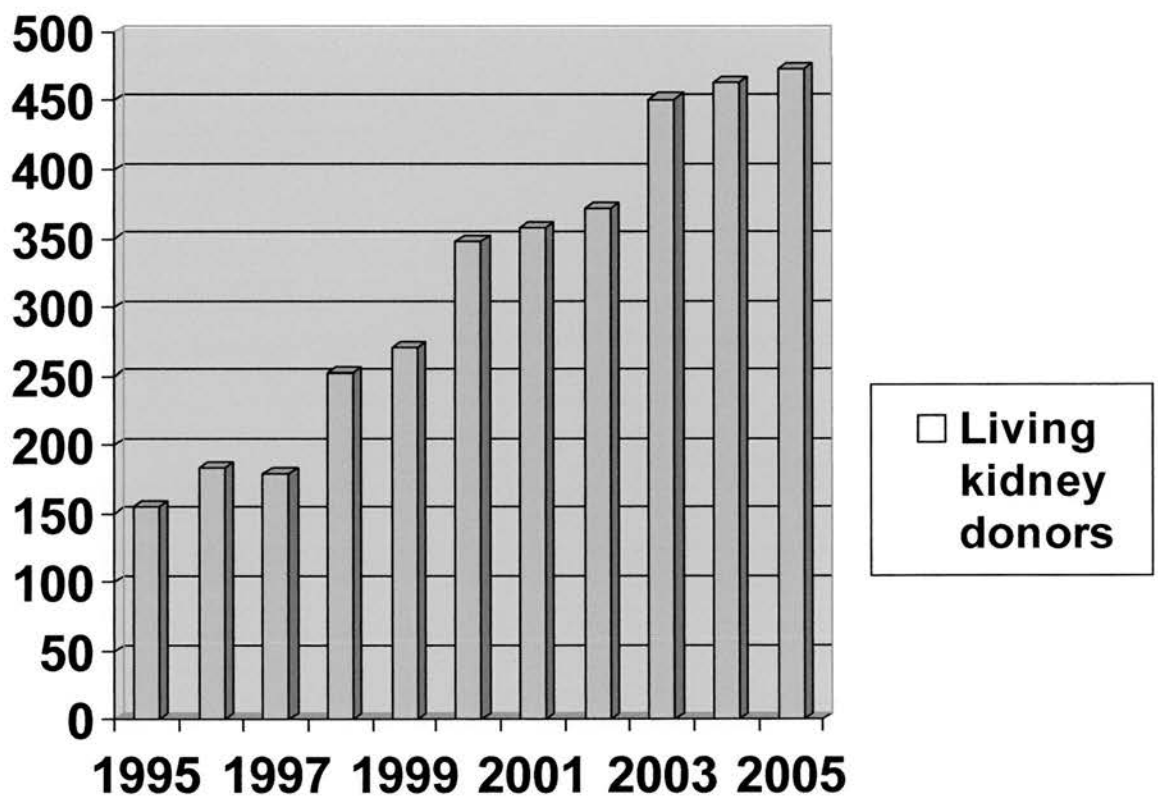
Following the Quinquennial Review of the United Kingdom Transplant Support Services Authority (UKTSSA) 1998-1999, the newly formed UK Transplant was awarded funding to maximize the number of solid organs donors within the UK. The 2001 UKT Business Plan aimed to increase the number of living donor transplants to 15-20% of the renal transplant waiting list. This was implemented by funding Living Renal Donor Co-ordinator Schemes throughout renal units in the UK. In November 2004 this initiative was reviewed, alongside others such as the non-heartbeating donor scheme and donor liaison scheme¹⁵⁴.

The living donor scheme was found to be extremely cost-effective, as the average increase of 63 donor kidneys per year would be expected to lead to 189 transplants over the three year period. This would translate into a cost benefit of £36 million over a nine year period (taking the nine-year median graft survival time of a transplant patient not requiring dialysis). The outcome of the review of the scheme was to recommend that UK

Transplant continued to fund living donor transplant co-ordinators in the long term¹⁵⁴.

Figure 20 displays the increase in living donor transplantation in the UK over the past 10 years.

Figure 20 - Number of living donors in the UK 1995-2005



Steady increase in number of living donor kidney transplants in the UK 1995-2005⁴⁶

The recommendations that UK Transplant continue to fund transplant co-ordinators in the renal units in the UK is positive and encouraging for this group of specialist nurses. Within the NHS there is a growing acceptance of the requirement for nurse practitioners to lead and assume responsibility for specialized programmes, supported by the Department of Health report 'Making a Difference' in 1999 recommending that experienced nurses be retained and rewarded to help improve quality of services¹⁵⁵

The study concerning the assessment of potential living donors showed that in 1999 only 20 of the 29 transplant centres responding employed a designated transplant co-ordinator/nurse practitioner to manage live donor transplantation, by 2002 all 25 centres performing live donor transplants had a living donor co-ordinator. The British Transplant Society Guidelines recommend that a designated live donor co-ordinator is considered optimal and that transplant co-ordinators play a key role in organizing the assessment and surgery for donor and/or recipient. Such individuals generally become closely acquainted with the patients and their families and may be best placed to provide the necessary support, even in the context of adverse events prior to or following transplantation⁵³.

Streamlining and having a key person to organize the assessment process may partly explain the increase in living donor transplantation over the past 5 years. In addition the provision of National information booklets and other local educational material alongside targeted patient information sessions and high profile media coverage has clearly had a positive impact on numbers. The recruitment of potential living kidney

donors depends on all members of the multi-disciplinary team working in close co-operation and ensuring equity of access to the potential of living donation. The methods of recruitment of living donors varies widely and is the subject of ethical debate. In some centres all potential recipients and their families are asked automatically whether they would consider living donation. In others a more passive approach is made with the provision of information about living donation but leaving the responsibility to the recipient and their family or friends to broach the subject. There is no real evidence over which is the best approach. A direct approach may recruit more potential donors but may make some individuals feel pressurized which is undesirable. A passive approach may miss donors but is likely to ensure that those that do come forward are well motivated. The best approach is probably somewhere in the middle ground with a more detailed explanation of the potential for living kidney donation but avoiding direct questioning. Such an approach requires that all members of the team are conversant in the issues surrounding living donation. Furthermore, no living donor programme can function without a surgeon willing to take responsibility for removing a kidney from a healthy person.

7.4: Selection of living donors

Our study of donor selection throughout the UK at two time points displayed that despite the introduction of national guidelines for the assessment and selection of living donors there still remains a disparity in both the physical and ethical selection process. This perhaps reflects the very real concern amongst some clinicians about living kidney

donation and their interpretation of minimum risk to the donor with maximum benefit to the recipient.

There is very little research concerning the donors who are ‘turned down’ for medical reasons – especially those borderline cases where, understandably, the safest course of action for the potential donor is not to undergo an operation. The donors who are advised not to donate for these physical reasons may feel angry or resentful that they have been denied the opportunity to improve the health and life of a close family member or friend. Anecdotally, again depending on the relationship, there can be a feeling of relief when the donor is told they should not proceed – one could argue these people should perhaps not be donating at all if they feel relieved that they have been found unsuitable, conversely it is surely a normal and appropriate human response to feel relieved by avoiding a major operation and associated implications. There is future scope for further study in this area, examining both the physical and emotional response to non-donation.

Perhaps the most interesting question that the assessment questionnaires raised was the balance of the rights of the donor (and recipient) and rights of the clinical team involved, especially the surgeon. Kidney donors are by definition otherwise healthy individuals and derive no health benefit from renal donation. There is an argument that donor selection should be made entirely separate from recipient influences, however the potential donor may contest this statement. For example, a woman in her 50s who has borderline renal function may be much more insistent on donating to her child or partner

rather than an age matched sibling. The incentive to donate, whether it be emotional or practical, can never be underestimated.

The General Medical Council has issued guidelines on the ethical considerations of gaining patients' consent. The potential living donor does fall into a different category to the majority of consent issues – not performing the procedure would physically be the best option for the live donor. The GMC states in the 1998 guidelines on Seeking Patients' Consent: the Ethical Considerations that 'it is for the patient, not the doctor, to determine what is in the patient's own best interests. Nonetheless, you may wish to recommend a treatment or a course of action to patients, but you must not put pressure on patients to accept your advice'¹⁵⁶. So where does this leave the surgeon who does not think it is in the potential donors' best interest to proceed to nephrectomy? Under the auspices of conscientious objection, the doctor can refuse to treat and refer to another clinician.

However, there has been a gradual shift away from a philosophy of paternalism to one that recognises the patient's right to make his or her own decisions about the care he or she receives. Respect for an individual's autonomy is the central reason that each person has the right to consent to or refuse treatment. Individuals can exercise their autonomy to make decisions about their care only if they have the necessary information about the choices available and the potential consequences of each course of action⁵¹.

Living donor transplantation continually presents complex medical dilemmas to which even the most experienced clinicians in transplantation cannot readily provide an

answer. This is partly due to the thorough investigations that the potential donor undergoes prior to donating. When a patient has a diseased organ or tissue that requires to be removed or repaired, there is a clear potential benefit for the operation to proceed and the patient undergoes a basic screening to ensure they are fit to survive an anaesthetic and operation. These issues become far more complex in the assessment of a live donor. The three areas of clinical assessment – immunological compatibility; renal function and general health can all require detailed investigation and raise decision making issues. The social and psychological issues have equal importance to physical assessment. One of the most ethically controversial areas within living donor transplant is providing the donor with a medical alibi – *e.g.* providing a reason for the donor not to proceed if they wish to withdraw at any time. This practice is universally accepted within the transplant community and rarely would a potential donor object to be offered this ‘opt-out’ clause. However, extreme care and caution has to be employed in this very sensitive area. No health professional should be put in the position of providing incorrect information to a family, even in the best interests of the donor. Likewise, the potential donor should not feel any added guilt at withdrawing by having to lie to the recipient.

Since 2001 UK Transplant have been collecting detailed information on all living kidney donors in the UK. This data set includes assessment information such as blood pressure, serum creatinine, haemoglobin, isotope glomerular filtration rate, estimated creatinine clearance, urinalysis, weight and height. Details of any co-morbid conditions have been requested and any further cardiac investigation required at time of assessment.

This information will provide a valuable database for assessment criteria, linked with the similar follow up data provided.

7.5: Quality of Life

Throughout the many and varied definitions of quality of life cited in the literature, there does appear to be a basic agreement that the measurement of quality of life depends upon an individual's subjective concept of their current situation in life. This is an important factor in the measurement of health-related issues, as two people with the same health status may have very different perceived qualities of life⁹⁴.

One of the key points in assessment of quality of life is the individual's perception. The 'disability paradox' has been demonstrated in some studies that have shown that patients with serious and persistent disabilities score their quality of life higher than many external observers would anticipate¹⁵⁷. This theory may be tested in the unique field of transplantation when a person with a chronic illness receives an intervention that improves physical disability and allows freedom from dialysis.

Within all forms of quality of life assessment there will always be debate and argument concerning the correct tool to utilize. The World Health Organisation Quality of Life questionnaire (WHOQOL) was selected for our study as it had been validated cross-culturally (and was to be utilized in two centres) and was designed to assess both well

and ill people. A renal disease specific questionnaire would have probably provided more detailed information concerning the recipients, but would not have provided any comparative measures to analyse. This was particularly and encouragingly substantiated in our findings that the donor physical domain quality of life was significantly higher than both the UK and world well average score pre donation.

We chose time points of pre-operation; six weeks post and one year post operation. The pre-donation time was within two weeks of the date of operation, and all pairs had completed the assessment and were in the final stages of preparation. This is obviously a time of high anxiety for any person awaiting an operation, and especially for the donor who does not physically require this surgery. It is therefore surprising that donor's scored so highly in the psychological domain, and may reflect a strong feel-good factor about the reason for donating.

The average recovery time after a major operation is expected to be 6-12 weeks, and all donors attend the transplant centre or referral centre for a post-operative assessment at around six weeks to assess recovery. Data collection for UK Transplant has indicated that for recovery from donor nephrectomy (open technique) to average between 8 and 12 weeks to return to previous level of fitness; thus the six weeks mark would indicate for the donor the latter stage of recovery. For the recipient, the level of kidney transplant function at one year is a reliable indicator of long-term graft survival. We chose one year as an end point for this study due to these two factors, although there would be interest in continuing and monitoring both donor and recipient for longer term.

The questionnaire design for the relationship issues was performed in consultation with Professor Power, University of Edinburgh, a member of the World Health Organisation Quality of Life Assessment Group and a leading expert in this area. A balance was sought to provide a range of options, both positive and negative for the donor and recipient. The questions were straightforward and avoided ambiguity and the format remained the same for all three questionnaires, although some of the questions necessarily required to differ. Possibly the most important factor in the completion of these questionnaires was to ensure that donor and recipient completed them separately from each other, as there would have been strong confounding factors if they had completed the questionnaires in each others presence.

The study was initially designed as a single centre study but was easily adopted by a further transplant centre. The reason for extending the study to Addenbrookes Hospital in Cambridge was to increase the numbers within in the study, rather than comparing any cultural or social differences. Both centres have similar practices and are size matched in regard to living donor transplantation. In retrospect, due to the nature of transplantation within the UK, with only 25 centres now performing living donor kidney transplantation, it may have been feasible for other centres to adopt the study and provide greater numbers.

From the fifty-two pairs who agreed to participate in the study there were 12 donors and 17 recipients who did not complete the questionnaire at all three time points (one

recipient died). The majority of the non-completers lived geographically further away and did not attend the transplant centres for follow-up and relied on postal completion. There was clearly an advantage of knowing the participants and ensuring the questionnaires were completed during a routine clinic visits. Average questionnaire response rates are 15% when relying on postal return and this was confirmed with our study. The fact that relationships had been built and the donors and recipients were in the hospital clinic may suggest an underlying coercion to complete the questionnaires. Conversely, due to the nature of living donor transplantation most people are very keen to assist and help inform future donors. This was certainly the common response within our clinic settings.

The value of our findings examining the quality of life and relationship issues are two fold. The assessment process is inevitably an extremely stressful time for donors, recipients and families. Within the clinic setting it is often described as a 'rollercoaster' of emotions ranging from anxiety, impatience, apprehension, sometimes anger and frustration. Contrary to usual hospital practice we ask the donors to move the assessment forward, ensuring that they are not being coerced by hospital staff to undergo investigations. The recipient has to take a sideline during the donor assessment, which sometimes must be hard to accept as the process is intended for their benefit. Other family members may feel excluded as the selected donor and recipient are the primary focus. During this assessment time the transplant team gains a privileged insight into family dynamics, coping mechanisms and motivation. This information may be invaluable at the time of transplant, especially if complications occur.

When all investigations are complete and the donor, recipient and family are willing to proceed with the operation, having been made aware of all the risks, both general and specific to that donor and recipient, a date is set for the transplant. At this time there is a subconscious shift of emphasis. The early part of the assessment sometimes appears to be spent informing the family of many negative aspects, with an acknowledgement of the benefits to the recipient. In many live donor pairs, when they are informed of the transplant date, the reality of the situation appears to impact. This is perhaps due to relief that the investigations are deemed satisfactory, but also that actually the operation is going to happen and there is a focus shift towards this. It is very important that the health professionals move with this shift, and support the decision made.

To this end, the information provided necessarily will concentrate on the practicalities of the admission arrangements, pre-dialysis, transport and family support. To date, there has not been a great amount of evidence to base psychological support at this time, other than reporting the retrospective studies such that donors do not regret donating, are not adversely affected in the long-term and most recipients experience an improved quality of life and health. This research has provided an in depth, evidence based study to report to donors, recipients and family members the expected outcome. The information can be summarized as follows:

Living kidney donors

- Careful donor selection ensures that individual's quality of life score is above the UK and world average (physical, psychological, social and environmental) pre donation.
- Six weeks after donation, physical quality of life is the same as a healthy person in the UK, returning to above average at one year. Psychological, social and environmental scores remain above the UK and World norm.
- The relationship with the recipient continues to improve over the year time period, relationships with family members does not alter significantly.
- Most kidney donors do not appear concerned about living with one kidney.
- Most kidney donors would donate again, if this were possible.

Transplant recipients from living donors

- Physical quality of life of patients with renal failure is significantly lower than that of the UK and World norm, psychological, social and environmental scores are similar.
- Within six weeks of a successful transplant, physical quality of life improves almost to the world average, within a year to the average well person in the UK.
- Relationships with both the donor and family members improves over the one year time period.
- The recipients have a high level of concern about the donor before the transplant, this is much reduced after the operation.

The second value of the findings is to provide evidence to health professionals in all areas of medicine. Ensuring equity of access to living kidney donation relies on awareness of all potential referring sources, including general practice, nephrology units and transplant centres. Reassurance that the selection of only the healthiest donors results in successful donation and transplantation is a strong and positive message. In addition, for those individuals who are found not to be suitable as donors due to physical or psychological reasons, the follow-up care is often passed back to general practitioners or referring units. Again this raises the question of how these individuals fare when not allowed to proceed. A further point that may be argued is that we are too selective with our donors, and that may deny people the right to enhance quality of life for the recipient. Only by selecting more marginal donors will this be proven – but this increases the risk of serious short and long term complications. Each individual case has to be assessed using the maxim of minimum risk to the donor with maximum benefit to the recipient⁵³. The death of the journalist Mike Hurewitz in Mount Sinai Hospital New York, following a living liver donation to his brother sent shock waves around the world. The story was featured on the front of Time magazine and on every major broadsheet newspaper. This adverse publicity was responsible for the suspension of the programme and a down turn in the number of individuals coming forward as living liver donors. We do not wish to be faced with a similar situation to this, as the UK wide impact of a donor death would seriously affect many programmes and as least temporarily reduce the number of live kidney donor transplants performed.

7.6: Follow-up

For many live kidney donors, due to relative absence of past medical history, admission to hospital for donor nephrectomy may be the first experience of surgery and the associated risks. The usual scenario would have been as supporter for their relative with renal failure. Preparation for this surgery therefore must include awareness of both the major and minor complications that may occur. Our study demonstrated that major complications in the two centres, Edinburgh and Cambridge during the retrospective study, are very rare, but on two occasion donors required blood transfusion for haemorrhage. Minor complications are more common than we had anticipated, and this study provided data both to provide information for donors and clinicians and also to review and change practice.

Possibly one of the most important observations has been the post-operative pyrexia in the absence of infection. Administering antibiotics unnecessarily is best avoided, and we have adopted a policy of not treating on the basis of pyrexia alone. Early physiotherapy intervention and mobilization has been instigated to reduce atelectasis, and although smoking was not correlated with a higher complication rate in our study due to low numbers, we do encourage potential donors to stop smoking prior to surgery.

The incidence of epidural complications, although low, gave rise to concern and review of policy was implemented. All donors are offered an epidural as standard post operative

pain relief and the hospital pain relief teams are informed of forthcoming donor nephrectomies. Epidurals are only performed by a member of a dedicated team of consultant transplant anaesthetists and the donors are reviewed by the hospital pain relief team on a twice daily basis. Constipation, although considered a minor complication, was a common complaint post-nephrectomy and prophylactic measures were introduced.

Future work is required to measure the impact of these changes in protocol. In addition, data collection by UK transplant concerning immediate peri and post operative complications in all donor nephrectomies throughout the UK will provide a large series of data, although this does depend on reporting criteria by centres and may just provide information on major complications.

If there is reasonable satisfaction that the immediate affect of living donor transplant is beneficial to both the donor and recipient in the short term, the longer term consequences also require examination. Further study aimed to establish the balance of follow-up required for this group of individuals. It is known that pre operation they are in good health and are estimated to have sufficient renal function to cope with one kidney in the long-term, what level of on-going monitoring is required?

As with assessment criteria, there was disparity throughout the UK with regards to donor follow-up. This has been addressed by UK Transplant collecting annual data concerning all living kidney donors, however it does depend on donors attending clinic or their general practitioner. Since UK transplant commenced this data collection 32% of donors

who donated in 2001 have been described as lost to follow-up. The reasons for this non-attendance at follow-up clinics may be due to a number of donors having traveled from abroad to donate a kidney here in the UK – with geographically spread families this is not uncommon. The other likely reason is healthy persons do not like taking time away from work to attend clinic when they do not feel unwell.

When the follow-up clinic was commenced we asked for donors to bring a 24 hour urine collection to estimate creatinine clearance. It soon became clear that this was an inconvenience and prompted a study concerning the estimation of renal function by alternative methods. With the study outcomes suggesting that Cockcroft and Gault estimation was more reflective of GFR than 24 hour urine collection for normal kidney function practice was altered. One further concern was protein measurement and agreement was made with the Clinical Chemistry department to perform urinary albumin quantification on any donor who had trace or above proteinuria on dipstick during routine follow-up.

As the follow-up clinic is a relatively new concept in terms of time, long term attendance rates will dictate the success of the venture. There appears to be a general acceptance of a nurse-led service. One aspect of the clinic being within the transplant setting rather than deferred is provision of support if the recipient graft fails. There can be a sense of loss or failure, despite the time interval and it is important that the donor has an opportunity to express emotions and discuss with a member of the transplant team.

Whilst the follow-up data for living kidney donors is encouraging, inconsistencies remain with insurance companies concerning the recovery period and associated short and long term risks. Potential donors are still advised to check with their insurance companies pre donation to ensure adequate cover in the short and long term. Donors should not be financially compromised by the act of donating a kidney. Recent guidelines from UK Health Departments have advocated reimbursing donors for loss of earnings as allowed by the 1989 Human Tissue Act (this also will be stated in the new Human Tissue Bills). In practice this is the responsibility of the health board of the recipient and not uniform across the UK. More work is required to ensure that donors receive equal treatment in this regard.

7.7: Summary

The chronic shortage of organs for transplantation has demanded that we look to all sources to increase organ availability. There is scope in the UK to increase the number of living donor transplants compared to other countries and the aim of this research was to examine current practice and improve standards of living kidney donor transplantation, so that this procedure can be confidently advocated as a treatment option. The study had five aims: 1) To establish the living donor assessment, selection criteria and follow up practice throughout transplant units in the United Kingdom; 2) To measure the impact on quality of life and relationship issues for both donor and recipient; 3) To ascertain if the act of donating a kidney causes short or long term physical or psychological harm; 4) To determine the optimum follow-up practice for living donors; 5) To explore whether we can improve the standards of living donor transplantation.

The study found that there remains variety in practice throughout the UK in procedures, although publication of national guidelines has provided a valuable framework. Careful donor and recipient selection results in successful outcome and should encourage living donor transplantation to continue and increase throughout the UK.

It was demonstrated that with rigorous donor assessment only those above UK average physical quality of life scores proceed to donation. The donors experience a transitory

decrease in quality of life following the operation and have a small risk of major and a higher risk of minor complications. Longer term the donors are not compromised by physical or psychological difficulties and experience an improved relationship with the recipient.

The clinical benefits of living donor transplant for the recipient are well-recognised and the assessment process appears to preclude those who may suffer psychological impairment from receiving a kidney from a living donor in our study group. The recipient enjoys an improved quality of life and relationships with both the donor and other family members. High level of concern about the donor decreases after the operation.

Annual follow-up is provided for those donors who wish to attend and the majority of donors do not worry about living with one kidney.

Practice has been adapted in response to findings and will be monitored to assess long-term effect. The study findings can be utilised to provide information for potential kidney donors, recipients and their families.

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LIVING DONOR ASSESSMENT AND FOLLOW UP QUESTIONNAIRE

PLEASE TICK APPROPRIATE BOX:

1. Does the assessment team use a written protocol? YES ☐
NO ☐

2. During the assessment work-up, are the donor and recipient seen:

TOGETHER ☐ SEPARATELY ☐ BOTH ☐

3. Are all potential donors assessed by:

Transplant surgeon YES ☐ NO ☐ Renal physician YES ☐ NO ☐

Transplant Co-ordinator YES ☐ NO ☐ Independent Medical Assessor YES ☐ NO ☐

Please circle person in overall charge of the assessment.

4. Are potential donors assessed by a psychologist?

Living related YES ☐ NO ☐ REFERRAL OPTION YES ☐ NO ☐

Living unrelated YES ☐ NO ☐ REFERRAL OPTION YES ☐ NO ☐

5. Is there an agreed time lapse between initial assessment and operation date?

NONE ☐ 3/12 ☐ 6/12 ☐ OTHER.....

6. When is the name of the recipient removed from the cadaveric list?

WHEN DONOR ASSESSMENT COMPLETE ☐ DATE OF OPERATION ☐

OTHER.....

7. Please tick ROUTINE clinical investigation requests:

BLOOD TESTS:

- | | |
|--|--------------------------|
| Full blood count (FBC)..... | <input type="checkbox"/> |
| Urea and electrolytes (U & Es)..... | <input type="checkbox"/> |
| Liver function tests (LFTs)..... | <input type="checkbox"/> |
| Uric Acid..... | <input type="checkbox"/> |
| Calcium..... | <input type="checkbox"/> |
| Phosphate..... | <input type="checkbox"/> |
| Random glucose..... | <input type="checkbox"/> |
| Fasting glucose..... | <input type="checkbox"/> |
| Total protein..... | <input type="checkbox"/> |
| Tissue typing..... | <input type="checkbox"/> |
| Lymphocytotoxic crossmatch..... | <input type="checkbox"/> |
| Flow cytometric crossmatch (FACS)..... | <input type="checkbox"/> |
| TPHA (Syphilis) | <input type="checkbox"/> |
| CMV..... | <input type="checkbox"/> |
| Hepatitis B..... | <input type="checkbox"/> |
| Hepatitis C..... | <input type="checkbox"/> |
| HIV | <input type="checkbox"/> |
| Epstein Barr Virus (EBV)..... | <input type="checkbox"/> |

INVESTIGATIONS:

- | | |
|---|--------------------------|
| Chest X-Ray..... | <input type="checkbox"/> |
| ECG..... | <input type="checkbox"/> |
| Urinalysis..... | <input type="checkbox"/> |
| Urine for microscopy..... | <input type="checkbox"/> |
| 24 Hour urine for protein & creatinine clearance. | <input type="checkbox"/> |
| Isotope Glomerular Filtration Rate (GFR)..... | <input type="checkbox"/> |
| Erect and Supine Blood Pressure(BP)..... | <input type="checkbox"/> |
| Serial BP monitoring..... | <input type="checkbox"/> |
| Ambulatory BP monitoring..... | <input type="checkbox"/> |
| Renal ultrasound..... | <input type="checkbox"/> |
| Intravenous pyelogram..... | <input type="checkbox"/> |
| Renal angiogram..... | <input type="checkbox"/> |

Please list other standard investigations:.....

8. EXCLUSION CRITERIA:

AGE: Please tick age of potential donors that would NEVER be considered:

<14yrs ☐ <16yrs ☐ <18yrs ☐ <21yrs ☐ <25yrs ☐
No minimum age ☐ Other.....

Please tick MAXIMUM age of potential donors:

55yrs ☐ 60yrs ☐ 65yrs ☐ 70yrs ☐ 75yrs ☐ 80yrs ☐
No maximum age ☐ Other.....

Would you consider child to parent donation? NEVER ☐ EXCEPTIONALLY ☐ ALWAYS ☐

FEMALES WITH CHILDBEARING POTENTIAL:

ALWAYS EXCLUDED ☐ SOMETIMES ACCEPTED ☐ ALWAYS ACCEPTED ☐

OBESITY: Please tick accepted EXCLUSION weight:

☐ <10% OVER IDEAL BODY WEIGHT
(eg. ideal body weight of 70kg - patient is <77kg)
☐ <15% OVER IDEAL BODY WEIGHT ☐
(eg. ideal body weight of 70kg - patient is <80.5kg)
☐ <20% OVER IDEAL BODY WEIGHT
(eg. ideal body weight of 70kg - patient is <84kg)

NO EXCLUSION CRITERIA ☐

OTHER.....

Please tick EXCLUSION result in the following scenario:

50 year old woman who weighs 60kg -

Creatinine Clearance: (mL/min/1.73m²)

<70 ☐ <80 ☐ <90 ☐ <100 ☐ <110 ☐ OTHER.....

DIABETES: Fasting blood glucose >6.0 YES ☐ NO ☐
 Family history of diabetes YES ☐ NO ☐
 Other exclusion criteria.....

HYPERTENSION: Does your unit define criteria for hypertension as a contraindication to living donation? YES ☐ NO ☐
If YES please define.....

WHO classification: mild hypertension:systolic 140-180 and/or diastolic 90-105(mmHg)
borderline hypertension: systolic 140-160 and/or diastolic 90-95

If we accept the World Health Organisation (WHO) classification for mild and borderline hypertension then please tick if your unit would EXCLUDE in the following scenario: A 40 year old fit male -

Normotensive taking one anti-hypertensive agent with no evidence of end organ damage (ie no left ventricular hypertrophy or microalbuminuria)	YES <input type="checkbox"/> NO <input type="checkbox"/>
Hypertensive on no medication with no evidence of end organ damage	YES <input type="checkbox"/> NO <input type="checkbox"/>
Borderline hypertension with evidence of end organ damage	YES <input type="checkbox"/> NO <input type="checkbox"/>
Borderline hypertension with no evidence of end organ damage	YES <input type="checkbox"/> NO <input type="checkbox"/>

OTHER: *Would you EXCLUDE a potential donor who:*

Has learning disabilities: Mild YES ☐ NO ☐ Moderate YES ☐ NO ☐
Is an alcohol abuser YES ☐ NO ☐ Is a smoker (>20/DAY) YES ☐ NO ☐

FOLLOW UP:

9. Are donors followed up by:
 TRANSPLANT UNIT ☐ INDEPENDENT MEDICAL ASSESSOR ☐
 GENERAL PRACTITIONER ☐ NO FOLLOW UP ☐ OTHER.....

10. One year after transplant, how often would the donor be reviewed?

6/12 ☐ 12/12 ☐ 24/12 ☐ OTHER.....

11. For how long would the donor be followed up?

1 YEAR ☐ 5 YEARS ☐ 10 YEARS ☐ LIFE ☐ OTHER.....

12. Is formal counselling available for the donor if the transplant fails?

YES ☐ NO ☐

13. How many renal transplants were performed in your unit in
1997 (1st Jan - 31st Dec)?

CADAVERIC.....

LIVING RELATED.....

LIVING UNRELATED.....

14. What size of population does your unit serve?.....

15. Who completed this questionnaire?

TRANSPLANT CO-ORDINATOR ☐ TRANSPLANT SURGEON ☐ BOTH ☐

OTHER.....

If you have a written protocol I would be most grateful if you would enclose a copy.

*Thank you for your time and co-operation in completing this questionnaire. Please
return to:*

Miss Jen Lumsdaine
Transplant Co-ordinator
Transplant Unit
Royal Infirmary of Edinburgh
Lauriston Place
EDINBURGH

Live Kidney Donor Assessment

1. How many renal transplants were performed in your unit in 2001 (1st Jan-31st Dec)?

Cadaveric Live related..... Live unrelated

2. Approximately how many potential donors are you currently assessing?.....

3. During the donor assessment process, please tick who of the following is routinely involved?:

	Live related	Live unrelated	Referral option
An Independent Medical Assessor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychiatrist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social worker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Which relationship pairings would your unit undertake? Please tick:

	Done in past	Perhaps in the future	Never
Parent to child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sibling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Child (>18yrs) to parent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grandparent to child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Child (>18yrs) to grandparent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Aunt/uncle to niece/nephew	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Niece/nephew to aunt/uncle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Partner to partner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Friend to friend	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Paired exchange (pending ULTRA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Altruistic (pending ULTRA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. During the live donor assessment, which of these investigations is performed as routine?

	Yes	No	Comment
Fasting blood glucose	<input type="checkbox"/>	<input type="checkbox"/>	
24hour urine for creatinine clearance	<input type="checkbox"/>	<input type="checkbox"/>	
24hour urine for protein quantification	<input type="checkbox"/>	<input type="checkbox"/>	
Exercise tolerance test	<input type="checkbox"/>	<input type="checkbox"/>	
Isotope GFR	<input type="checkbox"/>	<input type="checkbox"/>	
Renal angio	<input type="checkbox"/>	<input type="checkbox"/>	
Renal spiral CT	<input type="checkbox"/>	<input type="checkbox"/>	
Renal MRA	<input type="checkbox"/>	<input type="checkbox"/>	
Renal differential scan	<input type="checkbox"/>	<input type="checkbox"/>	

6. Does your unit perform the live donor transplant procedure:

Simultaneously ☐ Sequentially ☐ Comment.....

7. Do you offer laparoscopic donation if appropriate?

Yes ☐ No ☐

Number of laparoscopic donor nephrectomies in 2001

8. Funding issues:

Does the health board for the recipient reimburse donor expenses?

Yes ☐ No ☐ Comment

Is there any other means of reimbursing donors?

Yes ☐ No ☐ Comment

With the following scenarios, please complete responses after consultation and general agreement with the multi-disciplinary team:

9. A 45 year old woman wishes to donate a kidney. She is married with 3 children – age 9, 11 and 15 years old. Her corrected isotope GFR is 68 mls/min, creatinine clearance 80mls/min and differential scan shows equal kidney function. All other investigations are satisfactory. Please tick these two scenarios:

She wishes to donate to her 15 year old son, who is pre-dialysis.

Would you proceed? Yes ☐ No ☐

She wishes to donate to her friend, whom she has known since schooldays. There is no evidence of co-ercion, financial or otherwise:

Would you proceed? Yes ☐ No ☐

10. A 60 year old man wishes to donate to his 28 year old son. The donor has well controlled hypertension on one anti-hypertensive agent. All investigations are satisfactory other than the echocardiogram, which showed mild left ventricular hypertrophy. He is fully aware of these results and determined to proceed.

Would you proceed? Yes ☐ No ☐

11. A 24 year old woman wishes to donate to her 55 year old diabetic father. There are no other suitable family members, and her father has been on the transplant list for five years. Recently the recipient has been having problems with vascular access.

Would you proceed? Yes ☐ No ☐

Follow-up

12. Are donors offered long term follow-up? Yes ☐ No ☐

13. For what period of time? < 1 year ☐ 5 years ☐ 10 years ☐
Life ☐ Other.....

14. Who performs the follow-up? Please tick

- | | |
|------------------------------|--------------------------|
| Transplant co-ordinator | <input type="checkbox"/> |
| Transplant surgeon | <input type="checkbox"/> |
| Renal physician | <input type="checkbox"/> |
| Independent Medical Assessor | <input type="checkbox"/> |
| General practitioner | <input type="checkbox"/> |

Other

15. Does the follow-up include? Please tick:

- | | |
|----------------------------|--------------------------|
| Urinalysis | <input type="checkbox"/> |
| Blood pressure | <input type="checkbox"/> |
| Blood samples for: | |
| Urea & electrolytes | <input type="checkbox"/> |
| Haemoglobin | <input type="checkbox"/> |
| Glucose | <input type="checkbox"/> |
| 24hr urine collection for: | |
| Creatinine clearance | <input type="checkbox"/> |
| Protein quantification | <input type="checkbox"/> |
| Isotope GFR | <input type="checkbox"/> |

Other

16. Who completed this questionnaire? Please tick all personnel involved

- | | |
|--|--------------------------|
| Transplant Co-ordinator/Nurse Practitioner | <input type="checkbox"/> |
| Transplant Surgeon | <input type="checkbox"/> |
| Transplant Nephrologist | <input type="checkbox"/> |
| All of the above | <input type="checkbox"/> |
| Other | |

.....

Many thanks for completing this questionnaire

Please return to:

**Jen Lumsdaine; Transplant Unit, Royal Infirmary of Edinburgh
(addressed envelope enclosed)**

Estimation of creatinine clearance by formula

From the measured serum creatinine level (SCr) the creatinine clearance was estimated using three different formulae:

According to the Cockcroft-Gault formula:

$$CCl_{CG} = 0.85^{\text{sex}} \times \frac{(140 - \text{age}) \times \text{weight}}{72 \times \text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

The variable associated with the sex of a patient takes the value unity for a female and zero for a male. The multiplier of 88 is used to convert the measured SCr value from $\mu\text{mol/l}$ to mg/dl and age is in years.

The formula due to Jelliffe. A simple result gives:

$$CCl_J = 0.90^{\text{sex}} \times \frac{98 - 0.8(\text{age} - 20)}{\text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

The more complicated expression from Jelliffe and Jelliffe gives:

$$CCl_{J2} = \frac{E_{cor}}{14.4 \times \text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

where

$$E_{cor} = E_{ss} \times \frac{1344 - (43.76 \times \text{SCr})}{1344 - (43.76 \times 1.1)}$$

and

$$E_{ss} = 0.9^{\text{sex}} \times \text{weight} \times 0.95 \times (29.305 - 0.203\text{age})$$

WHOQOL - BREF



PROGRAMME ON MENTAL HEALTH WORLD HEALTH ORGANIZATION GENEVA

For office use only

	Equations for computing domain scores	Raw score	Transformed scores*	
			4-20	0-100
Domain 1	$(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18$ $\square + \square + \square + \square + \square + \square + \square$	=		
Domain 2	$Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)$ $\square + \square + \square + \square + \square + \square$	=		
Domain 3	$Q20 + Q21 + Q22$ $\square + \square + \square$	=		
Domain 4	$Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25$ $\square + \square + \square + \square + \square + \square + \square + \square$	=		

* Please see Table 4 on page 10 of the manual, for converting raw scores to transformed scores.

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I.D. number

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ABOUT YOU

Before you begin we would like to ask you to answer a few general questions about yourself: by circling the correct answer or by filling in the space provided.

What is your gender?	Male	Female	
What is you date of birth?	_____	/ _____	/ _____
	Day	/ Month	/ Year

What is the highest education you received?	None at all
	Primary school
	Secondary school
	Tertiary

What is your marital status?	Single	Separated
	Married	Divorced
	Living as married	Widowed

Are you currently ill?	Yes	No
If something is wrong with your health what do you think it is? _____ illness/ problem		

Instructions

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions.** If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks**. For example, thinking about the last two weeks, a question might ask:

		Not at all	Not much	Moderately	A great deal	Completely
		1	2	3	4	5
Do you get the kind of support from others that you need?						

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others as follows.

		Not at all	Not much	Moderately	A great deal	Completely
		1	2	3	4	5
Do you get the kind of support from others that you need?						

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

Please read each question, assess your feelings, and circle the number on the scale for each question that gives the best answer for you.

		Very poor	Poor	Neither poor nor good	Good	Very good
1 (G1)	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2 (G4)	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last two weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3 (F1.4)	To what extent do you feel that physical pain prevents you from doing what you need to do?	1	2	3	4	5
4 (F11.3)	How much do you need any medical treatment to function in your daily life?	1	2	3	4	5
5 (F4.1)	How much do you enjoy life?	1	2	3	4	5
6 (F24.2)	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7 (F5.3)	How well are you able to concentrate?	1	2	3	4	5
8 (F16.1)	How safe do you feel in your daily life?	1	2	3	4	5
9 (F22.1)	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

		Not at all	A little	Moderately	Mostly	Completely
10 (F2.1)	Do you have enough energy for everyday life?	1	2	3	4	5
11 (F7.1)	Are you able to accept your bodily appearance?	1	2	3	4	5
12 (F18.1)	Have you enough money to meet your needs?	1	2	3	4	5
13 (F20.1)	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14 (F21.1)	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither	Good	Very good
--	--	-----------	------	---------	------	-----------

				poor nor good		
15 (F9.1)	How well are you able to get around?	1	2	3	4	5

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16 (F3.3)	How satisfied are you with your sleep?	1	2	3	4	5
17 (F10.3)	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18(F12.4)	How satisfied are you with your capacity for work?	1	2	3	4	5
19 (F6.3)	How satisfied are you with yourself?	1	2	3	4	5
20(F13.3)	How satisfied are you with your personal relationships?	1	2	3	4	5
21(F15.3)	How satisfied are you with your sex life?	1	2	3	4	5
22(F14.4)	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23(F17.3)	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24(F19.3)	How satisfied are you with your access to health services?	1	2	3	4	5
25(F23.3)	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

		Never	Seldom	Quite often	Very often	Always
26 (F8.1)	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	1	2	3	4	5

Did someone help you to fill out this form?.....
How long did it take to fill this form out?.....

Do you have any comments about the assessment?

.....
.....

THANK YOU FOR YOUR HELP

ADDITIONAL QUESTIONS FOR THE DONOR – PRE OP

*Please indicate on the scale provided where your views lie, by marking the line with a cross
ie:*

Not at all |-----| **An extreme amount**

1. Has your relationship with the recipient improved following the issue of donation?

Not at all |-----| **An extreme amount**

2. Has the issue of donation had an adverse affect on your relationship?

Not at all |-----| **An extreme amount**

3. Has your relationship with other family members improved following the issue of donation of a kidney?

Not at all |-----| **An extreme amount**

4. Has the issue of donation had an adverse affect on your relationship with other family members?

Not at all |-----| **An extreme amount**

5. Have you concerns about the operation?

**Not
at all**



**An extreme
amount**

6. Have you concerns about the remaining kidney?

**Not
at all**



**An extreme
amount**

ADDITIONAL QUESTIONS FOR THE DONOR – POST OP

Please indicate on the scale provided where your views lie, by marking the line with a cross ie:

Not at all |-----| **An extreme amount**

1. Has your relationship with the recipient improved following donation?

Not at all |-----| **An extreme amount**

2. Has donation had an adverse affect on your relationship?

Not at all |-----| **An extreme amount**

3. Has your relationship with other family members improved following your donation of a kidney?

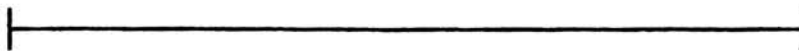
Not at all |-----| **An extreme amount**

4. Has your donation of a kidney had an adverse affect on your relationship with other family members?

Not at all |-----| **An extreme amount**

5. Have you suffered any financial loss due to the donation of a kidney?

Not
at all



An extreme
amount

6. Do your experience discomfort from the scar following kidney donation?

Not
at all



An extreme
amount

7. Do your worry about you remaining kidney?

Not
at all



An extreme
amount

8. If it were possible, would you donate a kidney again?

Definitely
No



Definitely
Yes

ADDITIONAL QUESTIONS FOR RECIPIENT – PRE AND POST OP

Please indicate on the scale provided where your views lie, by marking the line with a cross ie:

Not at all |-----| **An extreme amount**

1. Has the issue of kidney donation improved your relationship with the donor?

Not at all |-----| **An extreme amount**

2. Has the issue of a kidney donation had an adverse affect on your relationship with the donor?

Not at all |-----| **An extreme amount**

3. Has the issue of kidney donation improved your relationship with other members of your family/friends?

Not at all |-----| **An extreme amount**

4. Has the issue of kidney donation had an adverse affect on your relationship with other members of your family/friends?

Not at all |-----| **An extreme amount**

5. Do you have concerns about the welfare of the donor?

Not at all |-----| **An extreme amount**

Estimation of creatinine clearance by formula

From the measured serum creatinine level (SCr) the creatinine clearance was estimated using three different formulae:

According to the Cockcroft-Gault formula:

$$CC1_{CG} = 0.85^{\text{sex}} \times \frac{(140 - \text{age}) \times \text{weight}}{72 \times \text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

The variable associated with the sex of a patient takes the value unity for a female and zero for a male. The multiplier of 88 is used to convert the measured SCr value from $\mu\text{mol/l}$ to mg/dl and age is in years.

The formula due to Jelliffe. A simple result gives:

$$CC1_J = 0.90^{\text{sex}} \times \frac{98 - 0.8(\text{age} - 20)}{\text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

The more complicated expression from Jelliffe and Jelliffe gives:

$$CC1_{J2} = \frac{\text{Ecor}}{14.4 \times \text{SCr}} \times \frac{1.73}{\text{BSA}} \times 88$$

where

$$\text{Ecor} = \text{Ess} \times \frac{1344 - (43.76 \times \text{SCr})}{1344 - (43.76 \times 1.1)}$$

and

$$\text{Ess} = 0.9^{\text{sex}} \times \text{weight} \times 0.95 \times (29.305 - 0.203\text{age})$$

Appendix 7: Publications

1. Lumsdaine JA, Wigmore SJ, Forsythe JL. Live kidney donor assessment in the UK and Ireland. *Br J Surg* 1999;**86**:877-81.
2. Lumsdaine JA, Wigmore SJ, Wooton D, Stewart C, Akyol M, Forsythe JL. Establishing a transplant coordinator-led living kidney donor follow-up clinic. *Prog Transplant* 2003;**13**:138-41.
3. Clarke S, Lumsdaine JA, Wigmore SJ, Akyol M, Forsythe JL. Insurance issues in living kidney donation. *Transplantation* 2003;**76**:1008-9.
4. Lumsdaine JA, Wray A, Power MJ, Jamieson NV, Akyol M, Andrew Bradley J *et al*. Higher quality of life in living donor kidney transplantation: prospective cohort study. *Transpl Int* 2005;**18**:975-80.

Live kidney donor assessment in the UK and Ireland

J. A. Lumsdaine, S. J. Wigmore and J. L. R. Forsythe

Transplant Unit, Royal Infirmary of Edinburgh, Lauriston Place, Edinburgh EH3 9YW, UK

Correspondence to: Mr J. L. R. Forsythe

Background: The criteria and methods for assessing live kidney donors are not clear. This study was undertaken to establish whether there is a consensus regarding the organization and methods of assessment of living kidney donors by renal transplant centres in the UK and the Republic of Ireland.

Methods: All transplant centres in the UK and Ireland involved in living donor kidney transplantation were contacted by telephone survey followed by postal questionnaire.

Results: Considerable variation was observed in the organization of living kidney donor evaluation and the methods of assessment used. The upper and lower age limits considered acceptable for kidney donation were variable, with six of 29 centres setting no lower age limit and 11 setting no upper age limit. Four centres do not currently offer living donor kidney transplantation. Of the 29 centres involved with living donor transplantation ten had no protocol for donor assessment. A dedicated transplant coordinator/nurse practitioner was employed by 20 centres and ten routinely used an independent medical assessor to evaluate living related donors. The frequency and duration of donor follow-up after kidney donation also varied widely, with 18 centres providing life-time, seven limited and three no follow-up after initial postoperative assessment.

Conclusion: The wide variation in organizational structure and method of assessment of living kidney donors in the UK and Ireland supports the need for establishment of guidelines for this practice.

Paper accepted 10 March 1999

British Journal of Surgery 1999, 86, 877-881

Introduction

In the UK there was a 12 per cent reduction in the number of cadaveric renal transplants performed between 1990 and 1996. During the same period the number of patients waiting for kidney transplants increased by 48 per cent. The King's Fund report¹ in 1994 on the provision of donor organs for transplantation recommended that living donation should be expanded in an attempt to increase the availability of kidneys for transplantation. Between 1990 and 1996 live kidney donor transplantation increased by 81 per cent but still accounted for only 10 per cent of all renal transplants performed in 1996. This value is substantially lower than that reported by other European countries, such as Norway and Sweden where 39 and 27 per cent respectively of all renal transplants performed between 1991 and 1995 were living donor operations².

The benefits of live kidney donation for subsequent graft survival are well known. The 10-year graft survival rate estimate is 84 per cent for a human leucocyte antigen (HLA) identical sibling graft and 80 per cent for a one-haplotype identical graft, compared with 47 per cent for a cadaveric

transplant³. The graft survival of non-HLA-matched unrelated grafts is also superior to cadaveric transplantation, with a 6-year survival rate of 78 per cent³. While the benefits for the recipient are evident, surgical removal of a kidney from a healthy donor is not without risk. Previous studies have reported an operative mortality rate of 0.03–0.06 per cent in live kidney donors^{4–6}. Other risks include postoperative complications, long-term impairment of renal function, hypertension, psychological morbidity and loss of time and income⁷. The potential benefits for the live donor include an intensive medical investigation with undiagnosed medical problems being identified and treated plus the psychological benefit of organ donation⁷.

Live kidney donation is subject to legislation in the UK. The Human Organ Transplant Act 1989 and associated Regulations⁸ permit transplants from living related and unrelated donors, forbid any form of payment, but allow reimbursement of legitimate expenses to the donor. Where the donor and recipient are blood relatives, genetic confirmation is required. In other circumstances potential live donation must be referred to the UK Unrelated Live Transplant Regulatory Authority (ULTRA).

It has been suggested that the evaluation of potential live donors in the UK is often based on empirical rather than clinical evidence⁹. The purpose of the present study was to establish the organization, methods and criteria currently used for live donor assessment in the UK and Ireland.

Materials and methods

All 35 of the renal transplant centres in the UK and the Republic of Ireland were contacted. A structured questionnaire was sent to 31 centres which are involved in live donor transplantation or assessment, as identified by telephone survey. The questionnaire was designed to establish factors relating to donor assessment, exclusion criteria and follow-up. The centres identified a person responsible for organization of live donor transplantation to whom the questionnaire was sent.

Results

In the UK and Ireland 1503 cadaveric renal transplants and 165 live donor transplants were performed in 1997 by 35 transplant centres. Four centres do not perform living donor transplantation and of the 31 centres sent a questionnaire 29 responded. These centres had performed 1474 cadaveric renal transplants (98 per cent of the total for the UK and Ireland) and 150 live donor transplants (91 per cent of the total) of which nine were living unrelated transplants performed in seven centres. The questionnaire was completed by the transplant coordinator responsible for living donor transplants alone in 17 centres, with a transplant surgeon in four centres, with a renal physician in six centres, by a transplant surgeon alone in one centre and by a transplant surgeon and physician in one centre.

The organization of live donor assessment was examined. It was established that 19 centres had an established protocol, four were in the process of devising a protocol and six had no protocol. The assessment of live donors was led by a transplant surgeon in eight centres, renal physician in ten, transplant coordinator in one, transplant coordinator and renal physician in two, and in eight the responsible person was not identified. A designated transplant coordinator/nurse practitioner was used by 20 centres to manage live donor transplantation.

Donor and recipient were seen separately in all centres and were also interviewed together in 25 of the centres. Assessment by a psychiatrist or psychologist was routine for live related donors in five centres and for unrelated donors in six centres, and was a referral option in 13 centres for both live related and unrelated donors.

Recipients were removed from the cadaveric transplant waiting list when donor assessment was complete in four centres, on the date of operation in 17 centres, after discussion with recipient and donor in three centres and four centres had no defined policy; there was one non-respondent. Twenty centres did not have an agreed time period between initial assessment and date of operation. A period of 3 months was suggested by four centres and 6 months by five.

Investigations

Baseline investigations concerning the general fitness of the donor included full blood count, serum urea, creatinine and electrolyte estimation, liver function tests, chest radiography, electrocardiography and urinalysis; these tests were performed by all centres. Serum levels of calcium and phosphate were measured in 28 centres, uric acid in 20, thyroid function was determined in three, lipid profile in two and erythrocyte sedimentation rate in one centre. Investigations relating to diabetes, hypertension, infection screening, renal function, renal tract anatomy and histocompatibility are summarized in *Table 1*. Other investigations reported were exercise tolerance test (four centres), cervical smear for female donors (one) and bladder ultrasonography for older male donors (one).

Hypertension

Defined values for hypertension as an exclusion criterion had been established in 12 centres, but not in the majority. Using the World Health Organization criteria for hypertension (mild hypertension: systolic pressure of 140–180 mmHg and/or diastolic pressure of 90–105 mmHg) and the example of an otherwise fit 40-year-old man, nine centres would have excluded a donor taking one antihypertensive drug and who had no evidence of end-organ damage (no left ventricular failure or microalbuminuria). Thirteen centres would have excluded a donor with mild hypertension who was taking no medication and who had no end-organ damage. Twenty-one centres would have excluded a donor with borderline hypertension with evidence of end-organ damage, and nine would exclude such a donor if end-organ damage were absent.

Creatinine clearance

Using the scenario of a 50-year-old woman weighing 60 kg, levels of creatinine clearance below which exclusion from kidney donation should occur were considered to be 110 ml/min by two centres, 100 ml/min by four, 90 ml/

Table 1 Summary of investigations performed as part of living donor assessment

	No. of centres routinely performing investigation (n = 29)
Blood glucose	
Random blood glucose	27
Fasting blood glucose	9
Blood pressure	
Erect and supine blood pressure	23
Serial blood pressure	7
Ambulatory blood pressure	2
Infection screen	
Hepatitis A	1
Hepatitis B	29
Hepatitis C	29
Human immunodeficiency virus	29
Cytomegalovirus	29
Syphilis serology	15
Epstein-Barr virus	6
Renal function	
24-h urine for protein and creatinine clearance	23
Isotope glomerular filtration rate	24
Renal tract anatomy	
Angiography	28
Spiral computed tomography	1
Renal ultrasonography	23
Intravenous pyelography	14
Histocompatibility	
Tissue typing	29
Lymphocytotoxic cross-match	29
Flow cytometric cross-match	21

min by four, 80 ml/min by seven and 70 ml/min by two. No response to this question was received from ten centres.

Diabetes

A fasting blood glucose concentration of more than 6 mmol/l was considered an exclusion criterion for organ donation by 15 centres, a relative contraindication by two centres and not an exclusion criterion by ten; two centres did not respond. A family history of diabetes was considered an exclusion criterion by four centres but not by 23, it was considered to be a relative contraindication by one centre and one centre did not respond.

Obesity

There were no exclusion criteria for obesity in ten centres. Others excluded donors whose body-weight exceeded their ideal body-weight by 15–20 per cent (eight centres), by 10–15 per cent (six centres) and by less than 10 per cent (three centres). One centre defined a body mass index of more than

Table 2 Minimum and maximum ages of living kidney donors considered by transplant centres in the UK and Ireland

	No. of centres (n = 29)
Minimum age (years)	
None	6
16	4
18	13
21	6
Maximum age (years)	
None	11
65	5
70	7
75	6

40 or weight greater than 100 kg as exclusion criteria, while another excluded patients with a body mass index over 30.

Other exclusion criteria

A potential donor with a history of alcohol abuse would have been excluded by 15 centres but considered by ten and four did not respond. Smokers of more than 20 cigarettes per day would have been excluded as organ donors by six centres but considered by 20, three did not respond.

The exclusion criteria used by centres with respect to minimum and maximum acceptable age for the donor are illustrated in *Table 2*. Child to parent donation would be considered in 25 centres, although most considered this appropriate only in exceptional circumstances, and this relationship would not have been considered in four centres. Women of childbearing age were considered as donors by all centres. Donors with mild learning disability would be accepted as donors by 11 centres and excluded as donors by a further 11. Seven centres either stated that individual assessment would be required or did not answer the question. Potential donors with moderate learning disability were excluded by 20 centres but would be accepted by three and six did not respond.

Donor follow-up

Follow-up for live kidney donors was organized by the transplant unit in 28 centres and in 11 this care was coordinated jointly with the donors' general practitioners. One centre relied solely on the general practitioner for follow-up of the donor. The duration of follow-up of donors was reported as lifetime by 18 centres, 10 years by one centre, 5 years by two and 1 year by four. Following initial postoperative assessment no further follow-up was

arranged by three centres, and there was one non-respondent. One year after organ donation, donors were seen every 6 months in one centre, annually by 19 centres and biannually by one. In the event of an unsuccessful transplant, counselling facilities were provided for the donor by 15 centres but were not available in 12 centres; no information was provided by two centres.

Discussion

This study surveyed the practice of live donor assessment by centres in the UK and Ireland which were responsible for 98 per cent of cadaveric and 91 per cent of live donor kidney transplants performed in 1997. Four centres do not perform living donor transplantation and only seven performed a living unrelated transplant in 1997. This raises the possibility that patients in some centres may not have equal access to the benefits of living related and living unrelated transplantation. Those involved in purchasing renal healthcare for a population might reasonably ask that this modality of treatment be available to all willing and eligible patients. In addition the investigation of a donor and the definition of responsibility for that investigation would be considered very important, yet at the present time ten of 29 centres involved in live donor transplantation do not have an agreed protocol.

The assessment of live donors is variably led by renal transplant surgeons and physicians, raising the question of who should be responsible for this role. It could be argued that the responsibility for the donor ultimately lies with the surgeon and that there is a potential conflict of interest for the renal physician, since it is the renal recipient who derives clinical benefit from the procedure. All unrelated donors are required to be seen by an independent medical assessor. Although not a requirement under transplant legislation, independent medical assessors were used by ten centres to assess related donors. This perhaps reflects concern over the best representation of the donor's interests and the need to have a donor's advocate. All centres interview the donor separately from the recipient, implying cognizance of the importance of ascertaining the family dynamics⁹ and providing an opportunity for donors to raise specific concerns which they may not wish to share with recipients. This raises the question of whether greater involvement of psychologists would aid in clarification of these issues.

There are no data indicating the optimal time to remove recipients from the cadaveric transplant waiting list once live donor transplant has been agreed. The predicament exists between the avoidance of surgery on a healthy individual who will derive no clear direct benefit and the improved graft survival rate following live donor transplantation in comparison with cadaveric transplantation. In

addition, a cadaveric organ which is not used because the recipient is transplanted from a living donor source is then used to benefit another patient on the waiting list who may not have the option of living donor transplantation. Coupled with this issue is the question of whether it is useful to have a time lapse between initial donor assessment and subsequent transplantation. When a policy of leaving the recipient on the cadaveric transplant waiting list until the date of live donor transplantation is pursued in tandem with a long time lapse between donor assessment and transplantation, this will inevitably reduce the availability of cadaveric organs for transplantation since some recipients will be offered cadaveric transplant in the interval. In the present study the majority of centres did not identify a rigid time period but there was a consensus that assessment should not be hurried. Furthermore, there are individuals who have varying degrees of commitment to donation and it may be important to consider the views of the donor and recipient before deciding on the most appropriate time for removal of the recipient from the cadaveric transplant waiting list.

General investigations were performed by all centres but considerable variability was observed in the methods and thoroughness of infection screening, assessment of renal tract anatomy and renal function. No clear guidelines are available, based on sound clinical evidence, to indicate which factors should be considered as exclusion criteria for live organ donation. This is reflected in the variability in response to creatinine clearance as an exclusion criterion and the relatively high rate (ten of 29 centres) of non-responders to this question. The ethical dilemma of organ donation and informed consent from donors with learning difficulties is demonstrated by the low rate of acceptance (three of 29) of donors with moderate learning disability in the present study. In the USA, Bia *et al.*⁴ found that 46 per cent of centres do not have a policy regarding the use of donors with learning disabilities and 6 per cent accepted donors with severe intellectual impairment.

A further ethical dilemma relating to live donor transplantation arises with respect to the age of the donor. In the UK, 16 years is the legal age for provision of informed consent; however, in the present study six centres set no minimum age for organ donation. The most common age below which organ donation would not be considered was 18 years. At the other end of the scale, older donors have often been considered a greater operative risk and the functional results of grafts derived from older cadaveric donors are inferior to those from younger donors¹⁰. Data from a large series of living donors suggest that graft survival is also dependent on donor age¹¹. In the present study, 11 centres set no maximum age limit and a further six would consider live donation from donors over 70 years of age. In

spite of a move to include older donors, only 3 per cent of all living kidney donors reported by the United Network of Organ Sharing were over 60 years of age¹².

Child to parent donation would be considered in 25 of the 29 centres, and all would consider women of childbearing age as potential donors. Buszta *et al.*¹³ demonstrated that donor nephrectomy does not result in any increased risk of hypertension or hyperfiltration damage associated with subsequent pregnancy. Questions relating to the use of borderline or mildly hypertensive donors revealed that the most important consideration was the presence of end-organ damage.

A recent study highlighted the concern that nephrectomy may increase the subsequent risk of developing nephropathy and advocated thorough evaluation of potential donors for diabetes and diabetic nephropathy¹⁴. In the present study, however, ten centres did not consider a blood glucose concentration greater than 6 mmol/l to be an exclusion criterion for kidney donation.

Considerable variation was evident in the duration and frequency of follow-up of live donors. It is only relatively recently that 20-year data have become available on live kidney donors and, apart from the benefit of reassurance offered by long-term follow-up, such information on the live donor population would be of great value.

Currently live donor kidney transplantation is organized in a single national centre in both Norway and Finland. There are four centres involved in live donor transplantation in Sweden, each of which has an individual protocol, and research is currently in progress to establish the differences between them (J. Wadstrom, personal communication). Bia *et al.*⁴ discussed the importance of examining current practice patterns and defining issues that need further study in their report on the practice of living donor assessment in the USA. According to the United Organ Sharing Network (personal communication) there is still no national policy for living donor assessment in the USA. A similar situation also exists in Australia, where there are no national guidelines for living donor assessment. The British Transplantation Society and the Renal Association have established a working party to develop a national protocol to provide a consistent standard of care and assessment of live donors throughout the UK.

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Establishing a transplant coordinator-led living kidney donor follow-up clinic

Background—The long-term risks of renal failure and hypertension are statistically low for living kidney donors as a group, but can have serious consequences for the individual.

Objectives—To describe the experience with a transplant coordinator-led living donor follow-up clinic.

Method—Living kidney donors are reviewed on an annual basis by a designated coordinator (registered nurse). A 24-hour urine collection estimates renal function. Blood pressure and blood chemistry are measured and urinalysis performed.

Current health status and wound discomfort are assessed. Any medical problems identified are referred to a specialist hospital department or to the donor's family practitioner.

Results—Fifty-nine appointments were booked and 12 (20%) donors did not attend. Renal function was within acceptable limits for all attending donors. Three donors had raised blood glucose levels and 8 donors were hypertensive; all were referred to family practitioners. Forty-seven donors (35 new, 12 return) completed a questionnaire on the follow-up provided. Thirty-eight (81%) were satisfied with the follow-up, and 47 (100%) agreed this clinic provided adequate follow-up. Thirty-three (70%) donors stated they preferred that the transplant coordinator performed the follow-up, 3 (6%) preferred the family practitioner, and 11 (23%) had no preference.

Conclusions—There are many possible solutions to the provision of lifelong care of living kidney donors. The model of a transplant coordinator-led clinic appears to have a high degree of patient acceptance, perhaps because of the continuity of care provided by a known member of the transplant team. Further work is required to identify reasons for nonattendance. (*Progress in Transplantation*. 2003;13:138-141)

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Living kidney donation is an increasingly common mode of organ provision for kidney transplantation because of the shortage of cadaveric organs and increasing waiting lists. In certain European countries such as Norway, the number of living kidney transplantations approaches the number of cadaveric transplantations.¹ Although the reported risks of perioperative complications are low for living organ donors, there is a lack of good quality prospective data examining the long-term consequences of organ donation. Some studies have shown that the long-term risks of renal failure and hypertension are statistically low for living kidney donors as a group,² but can have serious consequences for the individual. In a recent study,³ the investigators found that of 28 transplant centers undertaking living donor transplantation in the United Kingdom and the Republic of Ireland, 18 undertook lifelong follow-up, 7 arranged limited follow-up, and 3 reported that they did not undertake

long-term follow-up. Similarly, in the United States, only 13% of United Network for Organ Sharing-approved centers recommend lifelong donor follow-up.⁴ Part of the difficulty in recommending policy on living kidney donor follow-up is that there are relatively few data on which to base such recommendations. In a somewhat circular argument, the lack of data lends weight to the call to establish a system of long-term donor follow-up. The nature of follow-up and who should undertake are also issues for debate. With acknowledgment to the lack of literature concerning long-term follow-up, the British Transplantation Society/Renal Association Guidelines for Living Kidney Donor Transplantation⁵ have advocated lifelong follow-up.

The purpose of this article is to report the implementation of a transplant coordinator-led living kidney donor follow-up clinic and to explain the basis for its establishment and agreed upon protocols.

Background

During the assessment of potential living kidney donors, the transplant team invests much time and effort ensuring each potential donor is medically assessed and fully informed of risks. Many believe that this duty of care should persist after donation. A recent study examining donors' perceptions of their health after kidney donation included statements of concern about the lack of contact with the transplant unit and nurse coordinator following surgery.⁶ Specific problems exist, which living kidney donors may encounter, particularly in the early postoperative period, that might not be obvious to healthcare professionals who are not involved in dealing with such patients on a regular basis. Therefore, the transplant unit seems to be the ideal base on which to center a clinic. The concept of establishing a follow-up clinic for living kidney donors was 2fold: first, to ensure that patients make a satisfactory recovery following donation and, second, to obtain adequate information, collected prospectively, of the long-term risks of kidney donation for future potential donors.

The aims of the clinic included the following:

- To provide continuity of care by the transplant team following donation
- To monitor renal function and blood pressure, as well as ongoing medical status
- To provide a setting in which the long-term welfare of a cohort of living kidney donors could be studied

Implementation

Our clinic was designed to be led by a transplant coordinator (qualified nurse) who has specific responsibility for living kidney donation and is actively involved in the assessment of all living kidney donors. Permission to implement the clinic was granted by the hospital authorities, which funded the clinic on a trial basis. In consultation with transplant surgeons and physicians, protocols were developed following standard guidelines for assessment and care in line with other existing protocols within the hospital.

Terms of Reference

Any problems related to abnormal blood test results, adverse events, or deterioration of renal function are referred to a consultant physician for review and further management. In addition, the nurse has access for referral to the transplant surgeons and physicians who were involved with the donor perioperatively. Consequently, the clinic can be safely manned by an experienced nurse who has security in the knowledge that there is a clear line of referral for senior medical advice should this be necessary.

Invitation to Attend Follow-Up

Since 1961, 150 living donor kidney transplantations have been undertaken at our unit. When possi-

ble, donors were traced and contacted initially by letter, inviting them to attend the clinic. All family practitioners were informed of the clinic and forthcoming appointment. We were concerned that patients who had donated a kidney some years before might worry when receiving a letter inviting them to attend a clinic after several years without follow-up. Therefore, the purpose of the invitation and the implementation of recent guidelines were quoted as reasons for establishing the clinic. If no response was received and the transplant recipient was known to the unit, the recipient was consulted whether further approaches should be made to initiate follow-up with the donor.

Clinic Organization

All kidney donors attend a transplant clinic 6 weeks after donation for review by a surgeon and transplant coordinator. Thereafter, donors are sent an annual appointment through the transplant coordinator clinic appointment system. Appointments are scheduled at 30-minute intervals to leave sufficient time for discussion. Donors are requested to commence a urine collection 24 hours before attendance, and containers for this purpose are mailed to them before their attendance.

Clinical investigations are summarized in the Table. Donors are asked specifically about problems with wound pain, and general problems that may be attributable to surgery. They are also given the opportunity to ask any questions that they may have regarding their donation or general health.

Following the appointment, any abnormal clinical results are discussed with an experienced physician. The results are reported to the donor's family practitioner and the donor by letter and on occasion the donor may be asked to reattend the clinic for further assessment.

Clinic Audit

An audit was conducted to establish whether patients were satisfied with arrangements for follow-up and the structure of the clinic. Patients were asked

Clinical investigations undertaken in all live donors

Blood pressure measurement
Urinalysis
Weight

Serum creatinine
Serum urea
Plasma glucose
Hemoglobin and blood count

Creatinine clearance
Urinary protein quantification

the following questions to which they were requested to respond yes or no:

1. Was it convenient for you to visit the hospital today?
2. Was there enough flexibility with your appointment date and time?
3. Did you feel that you received sufficient follow-up after donating your kidney?
4. Do you feel that this living kidney donor clinic will provide adequate follow-up?

In addition patients were given information that the clinic is run by a transplant coordinator with a consultant (specialist doctor) reviewing the results. Attendants were questioned whether they would prefer to be seen by the transplant coordinator with consultant review, a hospital doctor, or a family practitioner, or if they had no preference. Regarding the frequency of attendance for follow-up, attendants were asked whether they felt annual review was too often, not enough, or about right.

Results

Contact information was obtained for 47 living donors who donated between the years 1986 and 2000. Fifty-nine appointments were booked (47 new; 12 return) and 12 new (20%) donors did not attend. All the nonattendees were donors from the previous living donor program, who were not aware of the follow-up program.

Creatinine clearance, serum creatinine, and urea were within acceptable limits for all donors ($n=35$). Three donors had raised blood glucose levels, 8.1 mmol/L, 8.6 mmol/L, and 9.5 mmol/L, respectively (normal range 3.6-5.8 mmol/L), and were referred to their family practitioners for further management. Four donors had trace protein on dipstick urinalysis; however, laboratory measurements were undetectable. One donor was attending surgical clinic for ongoing wound problems and 2 additional donors were referred to the surgeons for review. Eight donors were found to be hypertensive at the clinic visit (170/90 mm Hg and 160/105 mm Hg), and all were referred to family practitioners. Two donors were taking antihypertensive agents.

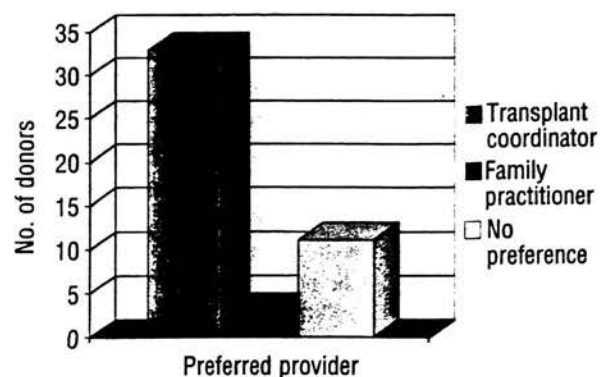
Forty-seven audit questionnaires, which asked about donors' views on the follow-up provided, were completed (35 new; 12 return). Forty-three (91%) donors stated it was convenient to visit the hospital, forty-six (98%) felt there was enough flexibility with the appointment, and 47 (100%) agreed it would provide adequate follow-up. Thirty-eight (81%) were satisfied with the follow-up they had received after kidney donation. When asked their preference with regard to who should undertake their follow-up, 33 (70%) donors preferred a transplant coordinator with consultant medical review, 3 (6%)

preferred a family practitioner, and 11 (23%) stated that they had no preference (see Figure). Forty-two donors (89%) felt an annual review was sufficient, with the remaining 5 (11%) stating that it was not frequent enough. If the donor found difficulty in attending the clinic because of the geographic distance, the local transplant unit or family practitioner was contacted and arrangements were made for donor follow-up using our model. In these circumstances, the results of investigations were sent to our unit for review.

Discussion

It is generally acknowledged that living kidney donation makes an important contribution to the problem of the international shortage of cadaveric organs. The success of a living donor program is dependent on low morbidity and mortality rates in the donors. The principal focus of living donor care has been on the assessment and perioperative care of the donor. A similar emphasis must also be placed on the long-term outlook of these individuals. Many centers in the United Kingdom, and other countries, do not have a structure for the follow-up of living donors. Part of the reason for this is that there is little evidence upon which to base recommendations for follow-up. Following guidelines that living donors should undergo life-long follow-up, we have initiated a clinic for the sole purpose of living kidney donor follow-up.

The high attendance rate suggests that kidney donors value the provision of long-term follow-up, with acknowledgment of ongoing care from the transplant team. The preliminary audit results confirm acceptability of a nurse-managed service. In addition, attendees commented that they appreciated the flexibility of our appointment system. It is essential that donors who live outside reasonable traveling distance to the transplant unit receive similar care to those attending the central unit; therefore, we have established a follow-up proforma that is provided to family



Donor preference for personnel involved in follow-up.

practitioners or district transplant units. Because many transplant centers aim to increase the number of living kidney donors, adequate resources should be made for follow-up. In addition, living donor follow-up clinics will enable improved quality of data that may be used to provide more accurate information for future living donors.

The referral pattern for ongoing surgical wound pain, raised blood glucose levels, and high blood pressure readings confirms a need for continual monitoring. Early detection may prevent long-term damage to the remaining kidney, and with minimally invasive testing this can be achieved.

The model for living donation presented here may not suit all centers, particularly those in which the geographic distance of the donors precludes their attendance at a central unit. We hope that the principles

that we have established will provide a useful model for other centers wishing to establish similar clinics.

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solely to monitor the infusion process, but also because they need intensive monitoring and surveillance and have a high risk of developing an infection if treated on an outpatient basis. One would be interested in knowing how these patients fared in the long term and whether they experienced an increased incidence of infection.

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TRANSPLANTATION

I appreciate the comments of Mr. Mahawar. As he correctly states, the manufacturers of Thymoglobulin (SangStat Medical Corporation, Fremont, CA) suggest only the use of a “high flow vein” and not specifically a central vein for the administration of Thymoglobulin. However, many published studies clearly indicate its administration through a central line (1, 2). I also agree with the author that many other centers are currently administering Thymoglobulin through peripheral access. The purpose of publishing this article was to more broadly endorse the practice of peripheral administration.
Although no formal statistical analysis was performed in regard to postadministration infection, no difference was noted in our ambulatory versus hospitalized patients.

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INSURANCE ISSUES IN LIVING KIDNEY DONATION

We have undertaken a study to ascertain the perspective of U.K. insurance companies to provision of insurance to living kidney donors. WHICH (consumer guide) and customer directories were used to identify the major life and health insurance providers in the United Kingdom, who were then invited to complete specific questionnaires.
The results were as follows: 14 life insurance companies, insuring approximately 6.5 million customers (79% of U.K. life insurance market), replied. When questioned regarding their policy if an existing customer should die during kidney donation, 13 of 14 stated that they would pay the agreed life insurance sum. One company did not provide an answer, as they had no experience of the situation and are currently deciding their position for future reference. No companies required to be informed by a customer of their intention to donate. Furthermore, all would accept new customers after previous kidney donation and would not charge an increased premium but indicated that time considerations since donation were a factor in assessing such customers (Table 1).
Regarding health insurance provision, seven major health insurance companies replied; however, one did not complete the questionnaire because they do not market

new business. Of the remaining six companies, half cover existing customers for kidney donation. Should an existing customer require a transplant, one company would pay recipient medical expenses and would also pay donor costs if the recipient and donor were both policy holders. All companies accept new customers after previous kidney donation, although two of six stipulate that they exclude any problems arising from donation. Two of six charge an increased rate and four of six do not. Time since donation is considered to be relevant for new customers, as shown in Table 1.
Insurance companies providing life insurance to almost

TABLE 1. Time since living kidney donation for new customers considered relevant by life and health insurers in the United Kingdom

	3 mo	6 mo	1–2 yr	Full recovery required time not specified	Total
Life insurers	2	7	2	3	14
Health insurers	1	1	1	2	5

80% of the life insurance policy holders in the United Kingdom would honor the terms of their agreement should a customer die as a consequence of live kidney donation. Premiums are not raised; therefore, kidney donation has no long-term financial implications regarding life insurance. When considering new customers applying for insurance, there were significant inconsistencies among both life and health insurers in the amount of time postdonation that respondents considered relevant. Deaths associated with live kidney donation are rare but occur predominantly in the perioperative period, as do the great majority of complications (1, 2), and so these time considerations could be considered to be without scientific foundation.

It has been postulated that the increased life expectancy in donor populations may be attributed to exclusion of concomitant illness by the rigorous assessment (3-5). Considering this, the reluctance of certain health insurers to provide medical expenses for donors or sickness benefit is disappointing. Equally, it could be argued that life insurance premiums should actually be reduced postdonation. Kidney donation may have financial implications for health insurance; however, the long-term effects of this are minimized because of the current structure of the National Health Service in the United Kingdom. The inconsistencies in many aspects of insurance provision to live kidney donors highlight the necessity to share information and strive for evidence-based practice from insurance providers.

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ERRATUM

In the article titled "Humorally Mediated Posttransplantation Septal Capillary Injury Syndrome as a Common Form of Pulmonary Allograft Rejection: A Hypothesis," published in the November 15, 2002 issue of *Transplantation*, volume 74, pp. 1273-1280, there are errors in the names of the fourth and eighth authors. The fourth author is stated as W. James Waldman, and the eighth author is stated as Patrick Ross. The correct names are W.J. Waldman and Patrick Ross Jr. The error is deeply regretted.

In the article titled "The Use of Non-Heart-Beating Donors for Isolated Pancreatic Islet Transplantation," published in the May 15, 2003 issue of *Transplantation*, volume 75, pp. 1423-1429, there is an error in the name of the twelfth author. The twelfth author is stated as Marko Vitamaniuk. The correct name is Marko Vataminiuk. The error is deeply regretted.

ORIGINAL ARTICLE

Higher quality of life in living donor kidney transplantation: a prospective cohort study

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kidney transplantation, live kidney donor, living donation, psychological outcome, quality of life, transplant outcome.

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Summary

This prospective, longitudinal cohort study investigated the effect of donating or receiving a kidney on quality of life and relationship dynamics. Forty donors and 35 recipients from two UK transplantation centres completed the World Health Organisation quality of life questionnaire (WHOQOL) with additional questionnaires before, 6 weeks and one year after operation. Before donation the donor mean quality of life score in the physical domain was 18.8. This was significantly higher than the UK value for a healthy person of 16.4 ($P < 0.001$). Six weeks after operation, donor score reduced to UK normative levels however improved again at one year (17.7). Recipient mean physical domain score before was 11.4, significantly lower than the UK norm ($P < 0.01$), increasing to 16.0 one year after. Both donor ($P < 0.009$) and recipient ($P < 0.05$) experienced a significant improvement in their mutual relationship. Recipients expressed anxiety about the donor before operation. Donors were not concerned about living with one kidney. We concluded that living kidney donation has no detrimental effect on the physical or psychological well being of donors one year after donation. Transplantation results in a major improvement in quality of life for the recipient. Most donors would donate again, if this were possible.

Introduction

For many patients with end-stage renal failure, a living donor kidney transplant offers the optimum treatment and can avoid the need for dialysis. The short- and long-term clinical benefits to the recipient, of a planned operation from a healthy donor with a brief cold ischaemic time are well documented and result in a superior graft survival compared with cadaveric kidney transplants [1–3]. The clinical benefits for the donor are less clear. During the donor assessment period previously undetected health problems may be identified and treated [4] and those who are deemed suitable donors enjoy reassurance concerning their health status [5].

Many previous studies examining quality of life issues in living donor kidney transplantation have been retrospective, or have focused on cohorts of either donors or recipients in isolation. In the US, one study revealed that live-kidney donors have similar or higher scores in all quality of life domains compared with the healthy US population and this observation was independent of the time since donation [6]. Another European study demonstrated that recipients of both living donor and cadaveric transplants had mean quality of life scores within one standard deviation (SD) of the norm for healthy individuals [7]. Although such studies are useful, there is a lack of objective longitudinal data examining the relationship dynamics and quality of life of both donor and recipient

as a pair through the process of living kidney donation and transplantation.

The definition of quality of life is much debated. The World Health Organization quality of life group (WHOQOL) describe 'an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns' [8]. One of the key points in assessment of quality of life is the individual's perception. The 'disability paradox' has been demonstrated in some studies that have shown that patients with serious and persistent disabilities score their quality of life higher than many external observers would anticipate [9]. This theory may be tested in the unique field of transplantation when a person with a chronic illness receives an intervention that improves physical disability and allows freedom from dialysis.

Relationships between donor, recipient and other family members provide a complex challenge. Feelings of guilt have more prominence in the recipients of transplants originating from living donors compared with cadaveric donors [7]. Individuals donating a kidney were less likely to say they would donate again (if it were possible) if they were donating to a person who was not a close blood relative or if the recipient of their kidney had died in the first year after transplantation [6]. Qualitative studies investigate complex relationships further, however, again many are retrospective and baseline findings may be difficult to compare.

The lack of good quality and objective data concerning quality of life outcomes for living kidney donors and transplant recipients means that it is difficult for health care professionals to provide advice to individuals considering kidney donation other than in the context of clinical measures such as graft survival and operative risk. The present study was designed specifically to investigate the effect of donating or receiving a kidney between donor and recipient pairings on their quality of life and relationship dynamics over time.

Methods

This prospective, longitudinal study was undertaken between January 2000 and January 2004 in the transplant units of the Royal Infirmary, Edinburgh and Addenbrooke's Hospital, Cambridge. Both centres had similar policies regarding donor and recipient selection, preoperative assessment and perioperative care. During the course of the study all donor nephrectomies were performed using an open technique with or without resection of the 12th rib. Only adult subjects (>18 years) were invited to participate as agreed with the local ethical approval committees. Both donor and recipient were

asked to complete two questionnaires each at three time points: before; 6 weeks after and 1 year after the live-donor transplant. The questionnaires included the WHOQOL Bref and an additional questionnaire examining relationship issues and concerns related to the procedure.

The WHOQOL Bref is a shortened form of the WHOQOL 100 and discriminates between 'well' and 'ill' subjects [8]. This was felt to be particularly important as many quality of life questionnaires are designed to assess the impact of illness on a population. As this study compared 'healthy' donors and patients with end-stage renal failure the WHOQOL Bref was selected. Data were also available to compare an age-matched well population in the UK. Twenty-six questions produce scores for four domains; physical, psychological, social and environmental, related to quality of life. The data were transformed and analysed with SPSS, using Mann-Witney or Kruskal-Wallis *H* test as appropriate (SPSS, Chicago, IL, USA). Data are presented as boxplots. Additional questionnaires were designed using a 10 cm linear-analogue scale with a member of the WHOQOL group (MJP) assisting in the development of the questions. The respondents were asked to state their response from minimum to maximum views on the scale. The recipients completed the same questionnaire at the same time points. The donor pre and postoperative questionnaire differed to encompass further social and economic issues experienced post-donation.

The donor and recipient pairs were asked to complete the questionnaire separately, to avoid conflict of responses. The majority were completed during routine clinic visits, although due to geographical limitations a number was posted and returned. The questionnaires were numerically coded and anonymous, although demographic details were requested.

Results

Patient inclusion and characteristics

From January 2000 to December 2002 fifty-two donor and recipient pairs consented to participate, three pairs declined. Twenty-three of the pairs were parent to adult child, 11 siblings, 16 spousal and 2 other nonrelated. Forty donors and 35 recipients completed the questionnaires at all three-time points. Individuals who did not complete questionnaires at all time points were excluded from analysis. Treatment for renal failure for the 35 recipients included 13 undergoing haemodialysis; 14 peritoneal dialysis and 8 were transplanted before renal replacement was necessary. All donors underwent open nephrectomy in this selected group. The mean age of the donor was 49 years (range 24–71 years), the recipient's mean age 37 years (range 19–54 years). Twenty-five donors were female and 15 donors male, 17 recipients were female and

Discussion

The goal of healthcare today is to improve the quality of life of patients, in addition to curing physical illness [10]. In 1946, the World Health Organization defined health as 'a state of complete physical, mental and social well being and not merely the absence of disease and infirmity' [11]. We have shown that removing a healthy organ from an individual causes short-term infirmity. This prospective, longitudinal study has demonstrated that living donor kidney transplantation does not adversely affect the longer term physical, psychological and social well-being of donors and substantially improves many aspects of the lives of recipients. The intense medical evaluation of potential living kidney donors results in the selection of only healthy, motivated individuals. In addition, all live-kidney donors are encouraged to achieve a level of fitness prior to donation. In the light of this it is perhaps not surprising that the physical domain score for donors before operation is above the national norm, confirming results of previous studies [12]. Likewise for the recipient, the physical improvement following transplantation confirms the benefit of this form of treatment.

The donors achieve a higher than normal psychological score predonation, decreasing at 6 weeks and 1 year, although remain at a level above the healthy population. It is possible that the selection of motivated individuals, coupled with the reassurance afforded by completion of the assessment process and the knowledge that the donor is fit to precede, improves psychological well being before donation. Similarly, for the recipient the knowledge that a transplant is imminent may increase a sense of psychological well being, in spite of the observed concerns that the recipient has for the safety of the donor.

No significant change in the social and environmental domain scores of either donor or recipient was observed. This is reassuring information for future donors that no adverse effect is caused by donation. It was anticipated that for the recipient, freedom from dialysis might have resulted in improved social and environmental interaction. The lack of change may reflect the fact that a number of transplants were 'pre-emptive', that is undertaken before dialysis was instituted or the intensity of the follow-up after transplantation. Benefits in social and environmental domains may become more apparent in the longer term, when the recipient does not require such intense follow-up.

Both the donor and recipient are informed in detail about the risks and benefits of living donor transplantation [13], with great emphasis on the risks to the donor undergoing a major operation. Thus recipient concerns about the donor are high before surgery, decreasing in

response to successful outcome and donor recovery. The donors continue to have a low level of concern about living with a solitary kidney. The emphasis during assessment that donation will only proceed with minimum risk to the donor and maximum benefit to the recipient [12] may partly reassure donors, alongside the life-long follow-up commitment of the transplant team.

The impact of living kidney donation does not appear to have adverse effects on relationships either between donor and recipient or with other family members. The rigorous evaluation process may preclude pairs with the potential for family conflict. Donors consider that the act of donation improves relationships with the recipient and to a lesser extent with family and friends, whose support is vital in the postoperative period.

This study has demonstrated that living donor kidney transplantation does not adversely affect the lives of donors and substantially improves many aspects of the lives of recipients. Careful donor selection allows those with a higher than normal physical quality of life to donate without impairing their physical or psychological status. As a group, the issue of donation and transplantation does not have an adverse effect on relationships, further work will analyse individual effect. The majority of living donors would donate again, providing reassuring information for potential donors.

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	Pre	6 weeks	1 year	UK well (n = 245)
Psychological	15.3 (12.7–6.0)	16.0 (14.7–6.7)	16.0 (15.3–6.7)	14.6 (12.0–7.5)
Social	16.0 (9.3–20.0)	16.0 (8.00–20.0)	16.0 (10.6–20.0)	15.4 (11.7–18.0)
Environmental	16.0 (8.5–10.0)	16.5 (10.0–19.5)	16.0 (9.0–19.5)	14.7 (11.4–16.7)

Table 2. World Health Organization quality of life group psychological, social and environmental domain scores for adult recipients of kidneys used for living donor kidney transplantation.

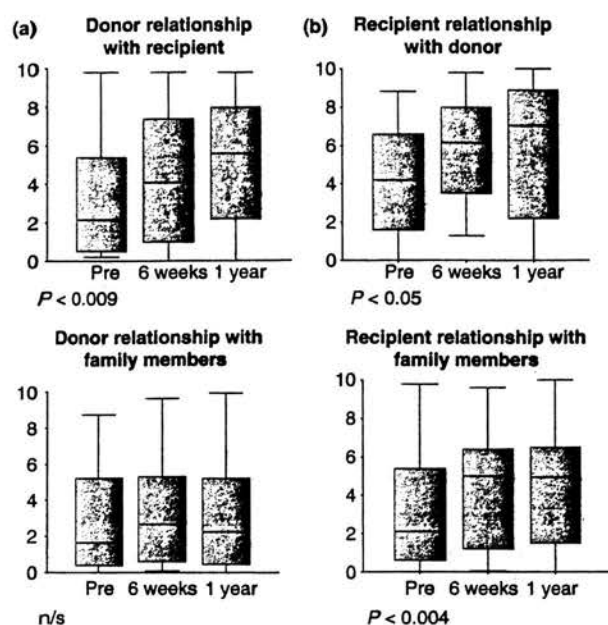


Figure 3 Changes in relationships between donor and recipient before and after living donor kidney transplantation. Donors (a) and recipients (b) both reported significant improvement in their relationships with each other following kidney donation and transplantation, respectively.

Relationship and social issues

The impact of the issue of live-kidney donation on the relationship of the pairing and family member and friends was addressed. The participants were asked to score on a linear analogue scale if the issue of live-kidney donation had improved their relationship. The scale measured 10 cm (0: not at all – 10: extreme amount). The donor and recipient were also asked if the issue of live-kidney donation had an adverse effect on relationship using the same scale. Both donor and recipient experienced a significant improvement in their mutual relationship (Fig. 3). When asked if the issue of live-kidney donation had any adverse effect on their relationship, the donor mean score was 0.8 (predonation), 1.7 (6 weeks post) and 2.2 (1 year post). The recipient mean score was lower: 0.6 (pretransplant), 0.6 (6 weeks after) and 0.7 (1 year later).

The recipients were asked to score their level of concern about the donor on the same 10 cm scale (Fig. 4).

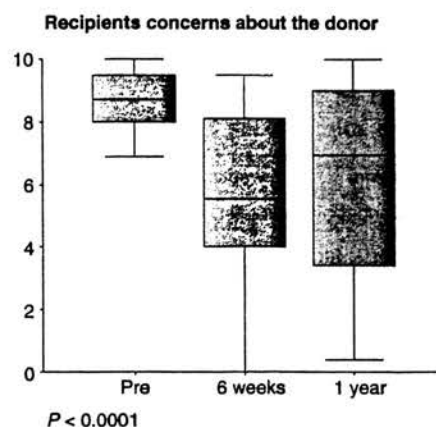


Figure 4 Recipients' concerns about the welfare of the donor before and after living donor kidney transplantation.

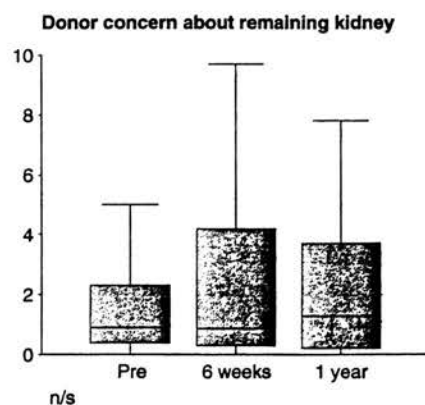


Figure 5 Level of concern of donors over their remaining kidney before and after living kidney donation.

Initially the recipients expressed a high level of concern (mean score 8.8) reducing at 6 week to 5.4. The donor was asked about their level of concern about their remaining kidney (Fig. 5). Consistently the donors did not worry about their remaining kidney – 0.8 (before the operation and 6 weeks after) and increasing to 1.0 (1 year after). Postoperatively, when asked about scar discomfort experienced the mean donor score was 2.0 at 6 weeks and 2.4 at 1 year. When asked, if it were possible, would they donate a kidney again, the donor mean score was 8.9 at 6 weeks and 9.3 at 1 year.

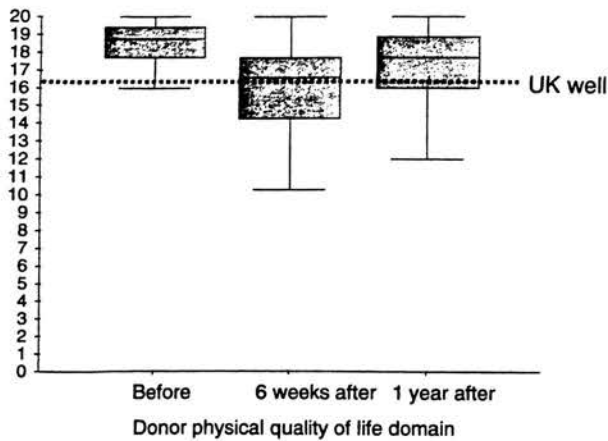


Figure 1 World Health Organization quality of life group physical domain scores for adult donors of kidneys before, 6 weeks and 1 year after kidney donation. The broken line represents the median physical domain score in an age- and sex-matched healthy UK population. There was a significant reduction in physical domain scores 6 weeks after donation ($\chi^2 = 17.2$; d.f. = 2; $P < 0.0001$ Kruskal–Wallis H test) with scores returning to predonation levels by 1 year.

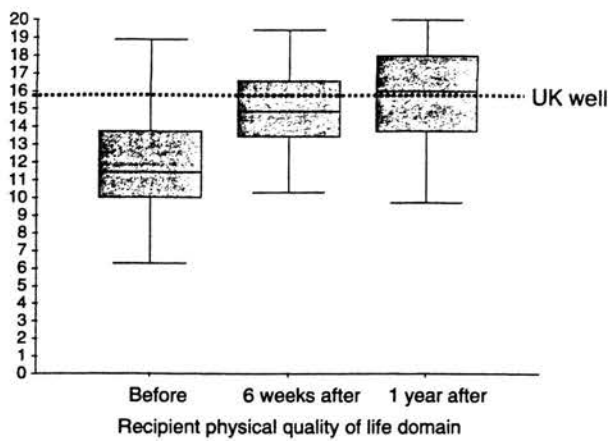


Figure 2 World Health Organization quality of life group physical domain scores for recipients of living donor kidney transplants before, 6 weeks and 1 year transplantation. The broken line represents the median physical domain score in an age- and sex-matched healthy UK population. Living donor kidney transplantation resulted in a significant increase in physical domain scores ($\chi^2=26.6$; d.f. =2; $P < 0.0001$ Kruskal–Wallis H test).

18 male. One recipient died within 1 year of transplant and one recipient received two live-donor transplants over the time period, the first having failed within 1 year. No donor suffered a major perioperative complication.

Quality of life assessment

The WHOQOL scores are reported in the four domains – physical, psychological, social and environmental. The mean physical scores for donors are summarized in Fig. 1 and further domain scores in Table 1. Recipients mean physical score are demonstrated in Fig. 2 and further domain scores in Table 2.

Within the physical domain the mean score for the donor was significantly higher than the UK normative value for a healthy person ($P < 0.001$). Six-week after donation, the physical domain scores of donors reduced to normative levels however improved again at 1 year, although did not reach predonation levels. By contrast the mean score for the recipient before transplantation was significantly lower than the UK normative value for a well person (11.4 pretransplant vs. 16.4 UK norm $P < 0.01$). The physical domain quality of life measure-

ment for the recipient significantly improved by 6 weeks and continued to improve such that by 1 year following living kidney transplantation it was not significantly different from the UK normative value for a well person.

Donor psychological domain scores before kidney donation were significantly greater than UK normative values for a well person ($P < 0.012$). Although the donor psychological domain mean decreased 6 weeks postdonation, this score remained significantly higher than the UK population normative value ($P < 0.001$). The recipient psychological domain scores before transplant were not significantly different from the UK normative value. However, following transplantation the psychological domain scores increased such that they were significantly higher than UK normative values at 6 weeks and 1 year ($P < 0.01$). There was no significant difference between the donor and recipient psychological domain scores 1 year after kidney donation or transplantation, respectively.

There were no significant changes in either the social or environmental domain scores of the donor or recipient groups before and after kidney donation or transplantation.

Table 1. World Health Organization quality of life group psychological, social and environmental domain scores for adult donors of kidneys used for living donor kidney transplantation.

	Before	6 weeks	1 year	UK well (n = 245)
Psychological	16.7 (16.0–8.0)	16.0 (14.7–6.7)	16.0 (14.0–7.2)	14.6 (12.0–7.5)
Social	17.3 (9.3–0.0)	17.3 (10.6–0.0)	17.3 (6.7–0.0)	15.4 (11.7–8.0)
Environmental	17.0 (12.0–0.0)	16.5 (9.00–0.0)	16.0 (11.0–0.0)	14.7 (11.4–6.7)

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